CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 077575

Name: Atorvastatin Calcium Tablets, 10 mg (base), 20 mg (base), 40 mg (base), and 80 mg (base)

Sponsor: Sandoz Inc.

Approval Date: May 29, 2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

CONTENTS

Reviews / Information Included in this Review

Approval Letter	**X**
Tentative Approval Letter	
Labeling	**X**
Labeling Review(s)	**X**
Medical Review(s)	
Chemistry Review(s)	**X**
Bioequivalence Review(s)	**X**
Statistical Review(s)	
Microbiology Review(s)	
Other Review(s)	
Administrative & Correspondence Documents	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077575

Sandoz Inc.
Attention: Bernadette Attinger
Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 11, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Atorvastatin Calcium Tablets, 10 mg (base), 20 mg (base), 40 mg (base), and 80 mg (base).

Reference is also made to your amendments dated October 12, November 15, and December 19, 2005; January 13, March 6, June 8, July 10, and October 2, 2006; April 3, and September 26, 2007; March 11, 2009 (2 submissions); March 1, and November 22, 2010; and March 24, May 31, June 14, June 22, July 13, August 30, October 3, and October 26 2011; and March 23, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Atorvastatin Calcium Tablets, 10 mg (base), 20 mg (base), 40 mg (base), and 80 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lipitor Tablets, 10 mg (base), 20 mg (base), 40 mg (base) and 80 mg (base), respectively, of Pfizer Inc. (Pfizer). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Pfizer's Lipitor Tablets, is subject to periods of patent protection. The following patents with their expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,686,104 (the '104 patent)	May 11, 2015
5,969,156 (the '156 patent)	January 8, 2017
6,126,971 (the '971 patent)	July 19, 2013

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Atorvastatin Calcium Tablets, 10 mg (base), 20 mg (base), 40 mg (base), and 80 mg (base), under this ANDA. You notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of any of these patents was brought against Sandoz within the statutory 45-day period.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

05/29/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Atorvastatin Calcium Tablets safely and effectively. See full prescribing information for Atorvastatin Calcium Tablets.

Atorvastatin Calcium Tablets for oral administration
Initial U.S. Approval: 1996

----------RECENT MAJOR CHANGES----------

Drug Interactions (7)	02/2012

----------INDICATIONS AND USAGE----------

Atorvastatin calcium tablet is an inhibitor of HMG-CoA reductase (statin) indicated as an adjunct therapy to diet to:

- Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without CHD, but with multiple risk factors (1.1).
- Reduce the risk of MI and stroke in patients with type 2 diabetes without CHD, but with multiple risk factors (1.1).
- Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in patients with CHD (1.1).
- Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (1.2).
- Reduce elevated TG in patients with hypertriglyceridemia and primary dysbetalipoproteinemia (1.2).
- Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) (1.2).
- Reduce elevated total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy (1.2).

Limitations of Use

Atorvastatin calcium tablets have not been studied in *Fredrickson* Types I and V dyslipidemias.

----------DOSAGE AND ADMINISTRATION----------

Dose range: 10 to 80 mg once daily (2.1).
Recommended start dose: 10 or 20 mg once daily (2.1).
Patients requiring large LDL-C reduction (>45%) may start at 40 mg once daily (2.1).
Pediatric starting dose: 10 mg once daily; maximum recommended dose: 20 mg once daily (2.2).

----------DOSAGE FORMS AND STRENGTHS----------

10, 20, 40, and 80 mg tablets (3).

----------CONTRAINDICATIONS----------

Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels (4.1).
Women who are pregnant or may become pregnant (4.3).
Nursing mothers (4.4).
Hypersensitivity to any component of this medication (4.2).

----------WARNINGS AND PRECAUTIONS----------

Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase when higher doses are used concomitantly with cyclosporine and strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, HIV protease inhibitors). Predisposing factors include advanced age (> 65), uncontrolled hypothyroidism, and renal impairment. Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported. In cases of myopathy or rhabdomyolysis, therapy should be temporarily withheld or discontinued (5.1, 8.5).

Liver enzyme abnormalities: Persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter (5.2).

A higher incidence of hemorrhagic stroke was seen in patients without CHD but with stroke or TIA within the previous 6 months in the atorvastatin calcium 80 mg group vs. placebo (5.5).

----------ADVERSE REACTIONS----------

The most commonly reported adverse reactions (incidence ≥ 2%) in patients treated with atorvastatin calcium in placebo-controlled trials regardless of causality were: nasopharyngitis, arthralgia, diarrhea, pain in extremity, and urinary tract infection (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc., at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Drug Interactions Associated with Increased Risk of Myopathy/Rhabdomyolysis (2.6, 5.1, 7, 12.3)

Interacting Agents	Prescribing Recommendations
Cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir)	Avoid atorvastatin
HIV protease inhibitor (lopinavir plus ritonavir)	Use with caution and lowest dose necessary
Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir)	Do not exceed 20 mg atorvastatin daily
HIV protease inhibitor (nelfinavir)	Do not exceed 40 mg atorvastatin daily

- Other Lipid-Lowering Medications: Use with fibrate products or lipid-modifying doses (≥1 g/day) of niacin increases the risk of adverse skeletal muscle effects. Caution should be used when prescribing with atorvastatin calcium (7).
- Digoxin: Patients should be monitored appropriately (7.8).
- Oral Contraceptives: Values for norethindrone and ethinyl estradiol may be increased (7.9).
- Rifampin should be simultaneously co-administered with atorvastatin calcium (7.7).

----------USE IN SPECIFIC POPULATIONS----------

- Hepatic impairment: Plasma concentrations markedly increased in patients with chronic alcoholic liver disease (12.3).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2012

FULL PRESCRIBING INFORMATION CONTENTS*

1. INDICATIONS AND USAGE
   1.1 Prevention of Cardiovascular Disease
   1.2 Hyperlipidemia
   1.3 Limitations of Use
2. DOSAGE AND ADMINISTRATION
   2.1 Hyperlipidemia
   2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
   2.3 Homozygous Familial Hypercholesterolemia
   2.4 Concomitant Lipid-Lowering Therapy
   2.5 Dosage in Patients With Renal Impairment
   2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or Certain Protease Inhibitors
3. DOSAGE FORMS AND STRENGTHS
4. CONTRAINDICATIONS
   4.1 Active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels
   4.2 Hypersensitivity to any component of this medication
   4.3 Pregnancy
   4.4 Nursing mothers
5. WARNINGS AND PRECAUTIONS
   5.1 Skeletal Muscle
   5.2 Liver Dysfunction
   5.3 Endocrine Function
   5.4 CNS Toxicity
   5.5 Use in Patients with Recent Stroke or TIA
6. ADVERSE REACTIONS
   6.1 Clinical Trial Adverse Experiences
   6.2 Postmarketing Experience
   6.3 Pediatric Patients (ages 10 to 17 years)
7. DRUG INTERACTIONS
   7.1 Strong Inhibitors of Cytochrome P450 3A4
   Clarithromycin
   Combination of Protease Inhibitors
   Itraconazole
   7.2 Grapefruit Juice
   7.3 Cyclosporine
   7.4 Gemfibrozil
   7.5 Other Fibrates
   7.6 Niacin
   7.7 Rifampin or other Inducers of Cytochrome P450 3A4
   7.8 Digoxin
   7.9 Oral Contraceptives
   7.10 Warfarin
   7.11 Colchicine
8. USE IN SPECIFIC POPULATIONS
   8.1 Pregnancy
   8.2 Nursing Mothers
   8.3 Pediatric Use
   8.4 Geriatric Use
   8.5 Hepatic Impairment
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
   12.1 Mechanism of Action
   12.2 Pharmacodynamics
   12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
   13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
   14.1 Prevention of Cardiovascular Disease
   14.2 Hyperlipidemia and Mixed Dyslipidemia
   14.3 Hypertriglyceridemia
   14.4 Dysbetalipoproteinemia
   14.5 Homozygous Familial Hypercholesterolemia
   14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
   17.1 Muscle Pain
   17.2 Liver Enzymes
   17.3 Pregnancy
   17.4 Breastfeeding

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, atorvastatin calcium tablets can be started simultaneously with diet.

1.1 Prevention of Cardiovascular Disease

In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin calcium tablets are indicated to:

- Reduce the risk of myocardial infarction
- Reduce the risk of stroke
- Reduce the risk for revascularization procedures and angina

In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin calcium tablets are indicated to:

- Reduce the risk of myocardial infarction
- Reduce the risk of stroke

In patients with clinically evident coronary heart disease, atorvastatin calcium tablets are indicated to:

- Reduce the risk of non-fatal myocardial infarction
- Reduce the risk of fatal and non-fatal stroke
- Reduce the risk for revascularization procedures
- Reduce the risk of hospitalization for CHF
- Reduce the risk of angina

1.2 Hyperlipidemia

Atorvastatin calcium tablets are indicated:

- As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb);
- As an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV);
- For the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet;
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable;
- As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
  a. LDL-C remains ≥ 190 mg/dL or
  b. LDL-C remains ≥ 160 mg/dL and:
     - there is a positive family history of premature cardiovascular disease or
     - two or more other CVD risk factors are present in the pediatric patient

1.3 Limitations of Use

Atorvastatin calcium tablets have not been studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons (*Fredrickson* Types I and V).

2. DOSAGE AND ADMINISTRATION

2.1 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb)

The recommended starting dose of atorvastatin calcium tablets is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of atorvastatin calcium tablets is 10 to 80 mg once daily. Atorvastatin calcium tablets can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses of atorvastatin calcium tablets should be individualized according to patient characteristics such as goal of therapy and response (see current *NCEP Guidelines*). After initiation and/or upon titration of atorvastatin calcium tablets, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.

2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10 to 17 years of age)

The recommended starting dose of atorvastatin calcium tablets is 10 mg/day; the maximum recommended dose is 20 mg/day (doses greater than 20 mg have not been studied in this patient population). Dose should be individualized according to the recommended goal of therapy [see current *NCEP Pediatric Panel Guidelines*, **CLINICAL PHARMACOLOGY (12)**, and **INDICATIONS AND USAGE (1.2)**]. Adjustments should be made at intervals of 4 weeks or more.

2.3 Homozygous Familial Hypercholesterolemia

The dosage of atorvastatin calcium tablets in patients with homozygous FH is 10 to 80 mg daily. Atorvastatin calcium tablets should be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) in these patients or if such treatments are unavailable.

2.4 Concomitant Lipid-Lowering Therapy

Atorvastatin calcium tablets may be used with bile acid resins. The combination of HMG-CoA reductase inhibitors (statins) and fibrates should generally be used with caution [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), DRUG INTERACTIONS (7)**].

2.5 Dosage in Patients With Renal Impairment

Renal disease does not affect the plasma concentrations nor LDL-C reduction of atorvastatin calcium tablets; thus, dosage adjustment in patients with renal dysfunction is not necessary [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), CLINICAL PHARMACOLOGY, Pharmacokinetics (12.3)**].

2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or Certain Protease Inhibitors

In patients taking cyclosporine or the HIV protease inhibitors (tipranavir plus ritonavir) or the hepatitis C protease inhibitor (telaprevir), therapy with atorvastatin calcium tablets should be avoided. In patients with HIV taking lopinavir plus ritonavir, caution should be used when prescribing atorvastatin calcium tablets and the lowest dose necessary employed. In patients taking clarithromycin, itraconazole, or in patients with HIV taking a combination of saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, therapy with atorvastatin calcium tablets should be limited to 20 mg, and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin calcium tablets are employed. In patients with HIV taking nelfinavir, therapy with atorvastatin calcium tablets should be limited to 40 mg, and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin calcium tablets are employed [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), Drug Interactions (7)**].

3. DOSAGE FORMS AND STRENGTHS

Light yellow, dappled, glossy, round biconvex, film-coated tablets containing 10, 20, and 40 mg atorvastatin calcium.

Light yellow, dappled, glossy, oval biconvex, film-coated tablets containing 80 mg atorvastatin calcium.

4. CONTRAINDICATIONS

4.1 Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels

4.2 Hypersensitivity to any component of this medication

4.3 Pregnancy

Women who are pregnant or may become pregnant. Atorvastatin calcium may cause fetal harm when administered to a pregnant woman. Serum cholesterol and triglycerides increase during normal pregnancy, and cholesterol or cholesterol derivatives are essential for fetal development. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. There are no adequate and well-controlled studies of atorvastatin calcium use during pregnancy, however in rare reports, congenital anomalies were observed following intrauterine exposure to statins. In rat and rabbit animal reproduction studies, atorvastatin revealed no evidence of teratogenicity. ATORVASTATIN CALCIUM SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS. If the patient becomes pregnant while taking this drug, atorvastatin calcium should be discontinued immediately and the patient apprised of the potential hazard to the fetus [see **USE IN SPECIFIC POPULATIONS (8.1)**].

4.4 Nursing mothers

It is not known whether atorvastatin is excreted into human milk; however a small amount of another drug in this class does pass into breast milk. Because statins have the potential for serious adverse reactions in nursing infants, women who require atorvastatin calcium treatment should not breastfeed their infants [see **USE IN SPECIFIC POPULATIONS (8.3)**].

5. WARNINGS AND PRECAUTIONS

5.1 Skeletal Muscle

Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin calcium and with other drugs in this class. A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Such patients merit closer monitoring for skeletal muscle effects.

Atorvastatin, like other statins, occasionally causes myopathy, defined as muscle aches or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values >10 times ULN. The concomitant use of higher doses of atorvastatin with certain drugs such as cyclosporine and strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, and HIV protease inhibitors) increases the risk of myopathy/rhabdomyolysis.

Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. Atorvastatin calcium therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

The risk of myopathy during treatment with drugs in this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, erythromycin, clarithromycin, the hepatitis C protease inhibitor telaprevir, combinations of HIV protease inhibitors, including saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, and fosamprenavir plus ritonavir, niacin, or azole antifungals. Physicians considering combined therapy with atorvastatin calcium and fibric acid derivatives, erythromycin, clarithromycin, a combination of saquinavir plus ritonavir, lopinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, azole antifungals, or lipid-modifying doses of niacin should carefully weigh the potential benefits and risks and should carefully monitor patients for any signs or symptoms of muscle pain, tenderness, or weakness, particularly during the initial months of therapy and during any periods of upward dosage titration of either drug. Lower starting and maintenance doses of atorvastatin should be considered when taken concomitantly with the aforementioned drugs [see **DRUG INTERACTIONS (7)**]. Periodic creatine phosphokinase (CPK) determinations may be considered in such situations, but there is no assurance that such monitoring will prevent the occurrence of severe myopathy.

Prescribing recommendations for interacting agents are summarized in **Table 1** [see also **DOSAGE AND ADMINISTRATION (2.6)**, **DRUG INTERACTIONS (7)**, **CLINICAL PHARMACOLOGY (12.3)**].

Table 1. Drug Interactions Associated with Increased Risk of Myopathy/Rhabdomyolysis

Interacting Agents	Prescribing Recommendations
Cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir)	Avoid atorvastatin
HIV protease inhibitor (lopinavir plus ritonavir)	Use with caution and lowest dose necessary
Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir*, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir)	Do not exceed 20 mg atorvastatin daily
HIV protease inhibitor (nelfinavir)	Do not exceed 40 mg atorvastatin daily

*Use with caution and with the lowest dose necessary (12.3)

Cases of myopathy, including rhabdomyolysis, have been reported with atorvastatin co-administered with colchicine, and caution should be exercised when prescribing atorvastatin with colchicine [see **DRUG INTERACTIONS (7.11)**].

Atorvastatin calcium therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).

5.2 Liver Dysfunction

Statins, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. **Persistent elevations (>3 times the upper limit of normal [ULN] occurring on 2 or more occasions) in serum transaminases occurred in 0.7% of patients who received atorvastatin calcium in clinical trials. The incidence of these abnormalities was 0.2%, 0.2%, 0.6%, and 2.3% for 10, 20, 40, and 80 mg, respectively.**

One patient in clinical trials developed jaundice. Increases in liver function tests (LFT) in other patients were not associated with jaundice or other clinical signs or symptoms. Upon dose reduction, drug interruption, or discontinuation, transaminase levels returned to or near pretreatment levels without sequelae. Eighteen of 30 patients with persistent LFT elevations continued treatment with a reduced dose of atorvastatin calcium.

It is recommended that liver enzyme tests be obtained prior to initiating therapy with atorvastatin calcium and repeated as clinically indicated. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including atorvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with atorvastatin calcium, promptly interrupt therapy. If an alternate etiology is not found, do not restart atorvastatin calcium.

Atorvastatin calcium should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contraindications to the use of atorvastatin calcium [see **CONTRAINDICATIONS (4.1)**].

5.3 Endocrine Function

Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including atorvastatin calcium.

Statins interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. Clinical studies have shown that atorvastatin calcium does not reduce basal plasma cortisol concentration or impair adrenal reserve. The effects of statins on male fertility have not been studied in adequate numbers of patients. The effects, if any, on the pituitary-gonadal axis in premenopausal women are unknown. Caution should be exercised if a statin is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

5.4 CNS Toxicity

Brain hemorrhage was seen in a female dog treated for 1 month at 120 mg/kg/day. Brain hemorrhage and optic nerve vacuolation were seen in another female dog that was sacrificed in moribund condition after 11 weeks of escalating doses up to 280 mg/kg/day. The 120 mg/kg dose resulted in a systemic exposure approximately 16 times the human plasma area-under-the-curve (AUC, 0–24 hours) based on the maximum human dose of 80 mg/day. A single tonic convulsion was seen in each of 2 male dogs (one treated at 10 mg/kg/day and one at 120 mg/kg/day) in a 2-year study. No CNS lesions have been observed in mice after chronic treatment for up to 2 years at doses up to 400 mg/kg/day or in rats at doses up to 100 mg/kg/day. These doses were 6 to 11 times (mouse) and 8 to 16 times (rat) the human AUC (0–24) based on the maximum recommended human dose of 80 mg/day.

CNS vascular lesions, characterized by perivascular hemorrhages, edema, and mononuclear cell infiltration of perivascular spaces, have been observed in dogs treated with other members of this class. A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion at a dose that produced plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose.

5.5 Use in Patients with Recent Stroke or TIA

In a post-hoc analysis of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study where atorvastatin calcium 80 mg vs. placebo was administered in 4,731 subjects without CHD who had a stroke or TIA within the preceding 6 months, a higher incidence of hemorrhagic stroke was seen in the atorvastatin calcium 80 mg group compared to placebo (55, 2.3% atorvastatin vs. 33, 1.4% placebo; HR: 1.68, 95% CI: 1.09, 2.59; p=0.0168). The incidence of fatal hemorrhagic stroke was similar across treatment groups (17 vs. 18 for the atorvastatin and placebo groups, respectively). The incidence of nonfatal hemorrhagic stroke was significantly higher in the atorvastatin group (38, 1.6%) as compared to the placebo group (16, 0.7%). Some baseline characteristics, including hemorrhagic and lacunar stroke on study entry, were associated with a higher incidence of hemorrhagic stroke in the atorvastatin group [see **ADVERSE REACTIONS (6.1)**].

6. ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the label:
Rhabdomyolysis and myopathy [see **WARNINGS AND PRECAUTIONS (5.1)**]
Liver enzyme abnormalities [see **WARNINGS AND PRECAUTIONS (5.2)**]

6.1 Clinical Trial Adverse Experiences

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the atorvastatin calcium placebo-controlled clinical trial database of 16,066 patients (8755 atorvastatin calcium vs. 7311 placebo; age range 10 to 93 years, 39% women, 91% Caucasians, 3% Blacks, 2% Asians, 4% other) with a median treatment duration of 53 weeks, 9.7% of patients on atorvastatin calcium and 9.5% of the patients on placebo discontinued due to adverse reactions regardless of causality. The five most common adverse reactions in patients treated with atorvastatin calcium that led to treatment discontinuation and occurred at a rate greater than placebo were: myalgia (0.7%), diarrhea (0.5%), nausea (0.4%), alanine aminotransferase increase (0.4%), and hepatic enzyme increase (0.4%).

The most commonly reported adverse reactions (incidence ≥ 2% and greater than placebo) regardless of causality, in patients treated with atorvastatin calcium in placebo controlled trials (n=8755) were: nasopharyngitis (8.3%), arthralgia (6.9%), diarrhea (6.8%), pain in extremity (6%), and urinary tract infection (5.7%).

Table 2 summarizes the frequency of clinical adverse reactions, regardless of causality, reported in ≥ 2% and at a rate greater than placebo in patients treated with atorvastatin calcium (n=8755), from seventeen placebo-controlled trials.

Table 2. Clinical adverse reactions occurring in ≥ 2% in patients treated with any dose of atorvastatin calcium and at an incidence greater than placebo regardless of causality (% of patients).

Adverse Reaction[a]	Any dose N= 8755	10 mg N= 3908	20 mg N= 188	40 mg N= 604	80 mg N= 4055	Placebo N=7311
Nasopharyngitis	8.3	8.0	5.3	7	4.2	8.2
Arthralgia	6.9	6.9	11.7	10.6	4.3	6.5
Diarrhea	6.8	7.3	6.4	14.1	5.2	6.3
Pain in extremity	6	8.5	3.7	9.3	3.1	5.9
Urinary tract infection	5.7	6.9	6.4	8	4.1	5.6
Dyspepsia	4.7	5.9	3.2	6	3.3	4.3
Nausea	4	3.7	3.7	7.1	3.8	3.5
Musculoskeletal pain	3.8	5.2	3.2	5.1	2.3	3.6
Muscle Spasms	3.6	4.6	4.8	5.1	2.4	3
Myalgia	3.5	3.6	5.9	9.4	2.7	3.1
Insomnia	3	2.8	1.1	5.3	2.6	2.9
Pharyngolaryngeal pain	2.3	3.9	1.6	2.8	0.7	2.1

a) Adverse Reaction ≥ 2% in any dose greater than placebo

Other adverse reactions reported in placebo-controlled studies include:

Body as a whole: malaise, pyrexia; *Digestive system:* abdominal discomfort, eructation, flatulence, hepatitis, cholestasis; *Musculoskeletal system:* musculoskeletal pain, muscle fatigue, neck pain, joint swelling; *Metabolic and nutritional system:* transaminases increase, liver function test abnormal, blood alkaline phosphatase increase, creatine phosphokinase increase, hyperglycemia; *Nervous system:* nightmare; *Respiratory system:* epistaxis; *Skin and appendages:* urticaria; *Special senses:* vision blurred, tinnitus; *Urogenital system:* white blood cells urine positive.

Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT)
In ASCOT [see **CLINICAL STUDIES (14.1)**] involving 10,305 participants (age range 40 to 80 years, 19% women; 94.6% Caucasians, 2.6% Africans, 1.5% South Asians, 1.3% mixed/other) treated with atorvastatin calcium 10 mg daily (n=5,168) or placebo (n=5,137), the safety and tolerability profile of the group treated with atorvastatin calcium was comparable to that of the group treated with placebo during a median of 3.3 years of follow-up.

Collaborative Atorvastatin Diabetes Study (CARDS)
In CARDS [see **CLINICAL STUDIES (14.1)**] involving 2,838 subjects (age range 39 to 77 years, 32% women; 94.3% Caucasians, 2.4% South Asians, 2.3% Afro-Caribbean, 1% other) with type 2 diabetes treated with atorvastatin calcium 10 mg daily (n=1,428) or placebo (n=1,410), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 3.9 years. No cases of rhabdomyolysis were reported.

Treating to New Targets Study (TNT)
In TNT [see **CLINICAL STUDIES (14.1)**] involving 10,001 subjects (age range 29 to 78 years, 19% women; 94.1% Caucasians, 2.9% Blacks, 1% Asians, 2% other) with clinically evident CHD treated with atorvastatin calcium 10 mg daily (n=5006) or atorvastatin calcium 80 mg daily (n=4995), there were more serious adverse reactions and discontinuations due to adverse reactions in the high-dose atorvastatin group (92, 1.8%; 446, 8.9%, respectively) as compared to the low-dose group (69, 1.4%; 404, 8.1%, respectively) during a median follow-up of 4.9 years. Persistent transaminase elevations (≥3 × ULN twice within 4 to 10 days) occurred in 62 (1.3%) individuals with atorvastatin 80 mg and in nine (0.2%) individuals with atorvastatin 10 mg. Elevations of CK (≥ 10 × ULN) were low overall, but were higher in the high-dose atorvastatin treatment group (13, 0.3%) compared to the low-dose atorvastatin group (6, 0.1%).

Incremental Decrease in Endpoints through Aggressive Lipid Lowering Study (IDEAL)
In IDEAL [see **CLINICAL STUDIES (14.1)**] involving 8,888 subjects (age range 26 to 80 years, 19% women; 99.3% Caucasians, 0.4% Asians, 0.3% Blacks, 0.04% other) treated with atorvastatin calcium 80 mg/day (n=4439) or simvastatin 20 to 40 mg daily (n=4449), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 4.8 years.

Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL)
In SPARCL involving 4731 subjects (age range 21 to 92 years, 40% women; 93.3% Caucasians, 3% Blacks, 0.6% Asians, 3.1% other) without clinically evident CHD but with a stroke or transient ischemic attack (TIA) within the previous 6 months treated with atorvastatin calcium 80 mg (n=2365) or placebo (n=2366) for a median follow-up of 4.9 years, there was a higher incidence of persistent hepatic transaminase elevations (≥ 3 × ULN twice within 4–10 days) in the atorvastatin group (0.9%) compared to placebo (0.1%). Elevations of CK (>10 × ULN) were rare, but were higher in the atorvastatin group (0.1%) compared to placebo (0%). Diabetes was reported as an adverse reaction in 144 subjects (6.1%) in the atorvastatin group and 89 subjects (3.8%) in the placebo group [see **WARNINGS AND PRECAUTIONS (5.5)**].

In a post-hoc analysis, atorvastatin calcium 80 mg reduced the incidence of ischemic stroke (218/2365, 9.2% vs. 274/2366, 11.6%) and increased the incidence of hemorrhagic stroke (55/2365, 2.3% vs. 33/2366, 1.4%) compared to placebo. The incidence of fatal hemorrhagic stroke was similar between groups (17 atorvastatin calcium vs. 18 placebo). The incidence of non-fatal hemorrhagic strokes was significantly greater in the atorvastatin group (38 non-fatal hemorrhagic strokes) as compared to the placebo group (16 non-fatal hemorrhagic strokes). Subjects who entered the study with a hemorrhagic stroke appeared to be at increased risk for hemorrhagic stroke [7 (16%) atorvastatin calcium vs. 2 (4%) placebo].

There were no significant differences between the treatment groups for all-cause mortality: 216 (9.1%) in the atorvastatin calcium 80 mg/day group vs. 211 (8.9%) in the placebo group. The proportions of subjects who experienced cardiovascular death were numerically smaller in the atorvastatin calcium 80 mg group (3.3%) than in the placebo group (4.1%). The proportions of subjects who experienced non-cardiovascular death were numerically larger in the atorvastatin calcium 80 mg group (5%) than in the placebo group (4%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of atorvastatin calcium. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions associated with atorvastatin calcium therapy reported since market introduction, that are not listed above, regardless of causality assessment, include the following: anaphylaxis, angioneurotic edema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), rhabdomyolysis, fatigue, tendon rupture, fatal and non-fatal hepatic failure, dizziness, depression, peripheral neuropathy, and pancreatitis.

There have been rare postmarketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally nonserious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).

6.3 Pediatric Patients (ages 10 to 17 years)

In a 26-week controlled study in boys and postmenarchal girls (n=140, 31% female; 92% Caucasians, 1.6% Blacks, 1.6% Asians, 4.8% other), the safety and tolerability profile of atorvastatin calcium 10 to 20 mg daily was generally similar to that of placebo [see **CLINICAL STUDIES (14.6)** and **USE IN SPECIAL POPULATIONS, Pediatric Use (8.4)**].

7. DRUG INTERACTIONS

The risk of myopathy during treatment with statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP 3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole) [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **CLINICAL PHARMACOLOGY (12.3)**].

7.1 Strong Inhibitors of CYP 3A4

Atorvastatin calcium is metabolized by cytochrome P450 3A4. Concomitant administration of atorvastatin calcium with strong inhibitors of CYP 3A4 can lead to increases in plasma concentrations of atorvastatin. The extent of interaction and potentiation of effects depend on the variability of effect on CYP 3A4.

Clarithromycin
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 80 mg with clarithromycin (500 mg twice daily) compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking clarithromycin, caution should be used when the atorvastatin calcium dose exceeds 20 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Combination of Protease Inhibitors
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium with several combinations of HIV protease inhibitors, as well as with the hepatitis C protease inhibitor telaprevir, compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking the HIV protease inhibitor tipranavir plus ritonavir, or the hepatitis C protease inhibitor telaprevir, concomitant use of atorvastatin calcium should be avoided. In patients taking the HIV protease inhibitor lopinavir plus ritonavir, caution should be used when prescribing atorvastatin calcium and the lowest dose necessary should be used. In patients taking the HIV protease inhibitors saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, the dose of atorvastatin calcium should not exceed 20 mg and should be used with caution [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Itraconazole
Atorvastatin AUC was significantly increased with concomitant

AND ADMINISTRATION, Dosage in Patients with Renal Impairment (2.5), **WARNINGS AND PRECAUTIONS**, **Skeletal Muscle (5.1)**].

Hemodialysis: While studies have not been conducted in patients with end-stage renal disease, hemodialysis is not expected to significantly enhance clearance of atorvastatin calcium since the drug is extensively bound to plasma proteins.

Hepatic Impairment: In patients with chronic alcoholic liver disease, plasma concentrations of atorvastatin calcium are markedly increased. C_{max} and AUC are each 4-fold greater in patients with Childs-Pugh A disease. C_{max} and AUC are approximately 16-fold and 11-fold increased, respectively, in patients with Childs-Pugh B disease [see **CONTRAINDICATIONS (4.1)**].

TABLE 3. Effect of Co-administered Drugs on the Pharmacokinetics of Atorvastatin

Co-administered drug and dosing regimen	Atorvastatin		
	Dose (mg)	Change in AUC[b]	Change in C_{max}[c]
[a]Cyclosporine 5.2 mg/kg/day, stable dose	10 mg QD for 28 days	↑ 8.7 fold	↑10.7 fold
[d]Tipranavir 500 mg BID/ ritonavir 200 mg BID, 7 days	10 mg, SD	↑ 9.4 fold	↑ 8.6 fold
[e]Telaprevir 750 mg q8h, 10 days	20 mg, SD	↑ 7.88 fold	↑ 10.6 fold
[e,f]Saquinavir 400 mg BID/ ritonavir 400 mg BID, 15 days	40 mg QD for 4 days	↑ 3.9 fold	↑ 4.3 fold
[a]Clarithromycin 500 mg BID, 9 days	80 mg QD for 8 days	↑ 4.4 fold	↑ 5.4 fold
[a]Darunavir 300 mg BID/ ritonavir 100 mg BID, 9 days	10 mg QD for 4 days	↑ 3.4 fold	↑ 2.25 fold
[a]Itraconazole 200 mg QD, 4 days	40 mg SD	↑ 3.3 fold	↑ 20%
[a]Fosamprenavir 700 mg BID/ ritonavir 100 mg BID, 14 days	10 mg QD for 4 days	↑ 2.53 fold	↑ 2.84 fold
[a]Fosamprenavir 1400 mg BID, 14 days	10 mg QD for 4 days	↑ 2.3 fold	↑ 4.04 fold
[a]Nelfinavir 1250 mg BID, 14 days	10 mg QD for 28 days	↑ 74%	↑ 2.2 fold
[a]Grapefruit Juice, 240 mL QD [g]	40 mg, SD	↑ 37%	↑ 16%
Diltiazem 240 mg QD, 28 days	40 mg, SD	↑ 51%	No change
Erythromycin 500 mg QID, 7 days	10 mg, SD	↑ 33%	↑ 38%
Amlodipine 10 mg, single dose	80 mg, SD	↑ 15%	↓ 12 %
Cimetidine 300 mg QID, 4 weeks	10 mg QD for 2 weeks	↓ Less than 1%	↓ 11%
Colestipol 10 mg BID, 28 weeks	40 mg QD for 28 weeks	Not determined	↓ 26%[h]
Maalox TC® 30 mL QD, 17 days	10 mg QD for 15 days	↓ 33%	↓ 34%
Efavirenz 600 mg QD, 14 days	10 mg for 3 days	↓ 41%	↓ 1%
[a]Rifampin 600 mg QD, 7 days (co-administered) [e]	40 mg SD	↑ 30%	↑ 2.7 fold
[a]Rifampin 600 mg QD, 5 days (doses separated) [e]	40 mg SD	↓ 80%	↓ 40%
[i]Gemfibrozil 600 mg BID, 7 days	40 mg SD	↑ 35%	↓ Less than 1%
[j]Fenofibrate 160 mg QD, 7 days	40 mg SD	↑ 3%	↑ 2%

a) Data given as x-fold change represent a simple ratio between co-administration and atorvastatin alone (i.e., 1-fold = no change). Data given as % change represent % difference relative to atorvastatin alone (i.e., 0% = no change).
b) See Sections 5.1 and 7 for clinical significance.
c) Greater increases in AUC (up to 2.5 fold) and/ or Cmax (up to 71%) have been reported with excessive grapefruit consumption (≥ 750 mL to 1.2 liters per day).
d) Single sample taken 8 to 16 h post dose.
e) Due to the dual interaction mechanism of rifampin, simultaneous co-administration of atorvastatin with rifampin is recommended, as delayed administration of atorvastatin after administration of rifampin has been associated with a significant reduction in atorvastatin plasma concentrations.
f) The dose of saquinavir plus ritonavir in this study is not the clinically used dose. The increase in atorvastatin exposure when used clinically is likely to be higher than what was observed in this study. Therefore, caution should be applied and the lowest dose necessary should be used.

TABLE 4. Effect of Atorvastatin on the Pharmacokinetics of Co-administered Drugs

Atorvastatin	Co-administered drug and dosing regimen		
	Drug/Dose (mg)	Change in AUC	Change in C_{max}
80 mg QD for 15 days	Antipyrine, 600 mg SD	↑ 3%	↓ 11%
80 mg QD for 14 days	[a]Digoxin 0.25 mg QD, 20 days	↑ 15%	↑ 20 %
40 mg QD for 22 days	Oral contraceptive QD, 2 months - norethindrone 1 mg - ethinyl estradiol 35 mcg	↑ 28% ↑ 19%	↑ 23% ↑ 30%
10 mg, SD	Tipranavir 500 mg BID/ritonavir 200 mg BID, 7 days	No change	No change
10 mg QD for 4 days	Fosamprenavir 1400 mg BID, 14 days	↓ 27%	↓ 18%
10 mg QD for 4 days	Fosamprenavir 700 mg BID/ ritonavir 100 mg BID, 14 days	No change	No change

a) See **Section 7** for clinical significance.

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
In a 2-year carcinogenicity study in rats at dose levels of 10, 30, and 100 mg/kg/day, 2 rare tumors were found in muscle in high-dose females: in one, there was a rhabdomyosarcoma and, in another, there was a fibrosarcoma. This dose represents a plasma AUC (0-24) value of approximately 16 times the mean human plasma drug exposure after an 80 mg oral dose.

A 2-year carcinogenicity study in mice given 100, 200, or 400 mg/kg/day resulted in a significant increase in liver adenomas in high-dose males and liver carcinomas in high-dose females. These findings occurred at plasma AUC (0-24) values of approximately 6 times the mean human plasma drug exposure after an 80 mg oral dose.

In vitro, atorvastatin was not mutagenic or clastogenic in the following tests with and without metabolic activation: the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the HGPRT forward mutation assay in Chinese hamster lung cells, and the chromosomal aberration assay in Chinese hamster lung cells. Atorvastatin was negative in the *in vivo* mouse micronucleus test.

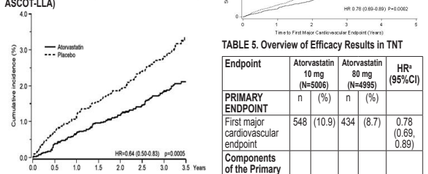
Studies in rats performed at doses up to 175 mg/kg (15 times the human exposure) produced no changes in fertility. There was aplasia and aspermia in the epididymis of 2 of 10 rats treated with 100 mg/kg/day of atorvastatin for 3 months (16 times the human AUC at the 80 mg dose); testis weights were significantly lower at 30 and 100 mg/kg and epididymal weight was lower at 100 mg/kg. Male rats given 100 mg/kg/day for 11 weeks prior to mating had decreased sperm motility, spermatid head concentration, and increased abnormal sperm. Atorvastatin caused no adverse effects on semen parameters, or reproductive organ histopathology in dogs given doses of 10, 40, or 120 mg/kg for two years.

14. CLINICAL STUDIES
14.1 Prevention of Cardiovascular Disease
In the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), the effect of atorvastatin calcium on fatal and non-fatal coronary heart disease was assessed in 10,305 hypertensive patients 40 to 80 years of age (mean of 63 years), without a previous myocardial infarction and with TC levels ≤251 mg/dL (6.5 mmol/L). Additionally, all patients had at least 3 of the following cardiovascular risk factors: male gender (81.1%), age >55 years (84.5%), smoking (33.2%), diabetes (24.3%), history of CHD in a first-degree relative (26%), TC:HDL >6 (14.3%), peripheral vascular disease (5.1%), left ventricular hypertrophy (14.4%), prior cerebrovascular event (9.8%), specific ECG abnormality (14.3%), proteinuria/albuminuria (62.4%). In this double-blind, placebo-controlled study, patients were treated with anti-hypertensive therapy (Goal BP <140/90 mm Hg for non-diabetic patients; <130/80 mm Hg for diabetic patients) and allocated to either atorvastatin calcium 10 mg daily (n=5168) or placebo (n=5137), using a covariate adaptive method which took into account the distribution of nine baseline characteristics of patients already enrolled and minimized the imbalance of those characteristics across the groups. Patients were followed for a median duration of 3.3 years.

The effect of 10 mg/day of atorvastatin calcium on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of coronary events [either fatal coronary heart disease (46 events in the placebo group vs. 40 events in the atorvastatin calcium group) or non-fatal MI (108 events in the placebo group vs. 60 events in the atorvastatin calcium group)] with a relative risk reduction of 36% [based on incidences of 1.9% for atorvastatin calcium vs. 3% for placebo), p=0.0005 (see **Figure 1**)]. The risk reduction was consistent regardless of age, smoking status, obesity, or presence of renal dysfunction. The effect of atorvastatin calcium was seen regardless of baseline LDL levels. Due to the small number of events, results for women were inconclusive.

Figure 1: Effect of Atorvastatin Calcium 10 mg/day on Cumulative Incidence of Non-Fatal Myocardial Infarction or Coronary Heart Disease Death (in ASCOT-LLA)



Atorvastatin calcium also significantly decreased the relative risk for revascularization procedures by 42%. Although the reduction of fatal and non-fatal strokes did not reach a pre-defined significance level (p=0.01), a favorable trend was observed with a 26% relative risk reduction (incidences of 1.7% for atorvastatin calcium and 2.3% for placebo). There was no significant difference between the treatment groups for death due to cardiovascular causes (p=0.51) or noncardiovascular causes (p=0.17).

In the Collaborative Atorvastatin Diabetes Study (CARDS), the effect of atorvastatin calcium on cardiovascular disease (CVD) endpoints was assessed in 2838 subjects (94% white, 68% male), ages 40 to 75 with type 2 diabetes based on WHO criteria, without prior history of cardiovascular disease and with LDL ≤ 160 mg/dL and TG ≤ 600 mg/dL. In addition to diabetes, subjects had 1 or more of the following risk factors: current smoking (23%), hypertension (80%), retinopathy (30%), or microalbuminuria (9%) or macroalbuminuria (3%). No subjects on hemodialysis were enrolled in the study. In this multicenter, placebo-controlled, double-blind clinical trial, subjects were randomly allocated to either atorvastatin calcium 10 mg daily (1429) or placebo (1411) in a 1:1 ratio and were followed for a median duration of 3.9 years. The primary endpoint was the occurrence of any of the major cardiovascular events: myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke. The primary analysis was the time to first occurrence of the primary endpoint.

Baseline characteristics of subjects were: mean age of 62 years, mean HbA, 7.7%; median LDL-C 120 mg/dL; median TC 207 mg/dL; median TG 151 mg/dL; median HDL-C 52 mg/dL.

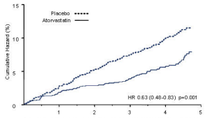
The effect of atorvastatin calcium 10 mg/day on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of major cardiovascular events (primary endpoint events) (83 events in the atorvastatin calcium group vs. 127 events in the placebo group) with a relative risk reduction of 37%, HR 0.63, 95% CI (0.48, 0.83) (p=0.001) (see **Figure 2**). An effect of atorvastatin calcium was seen regardless of age, sex, or baseline lipid levels.

Atorvastatin calcium significantly reduced the risk of stroke by 48% (21 events in the atorvastatin calcium group vs. 39 events in the placebo group), HR 0.52, 95% CI (0.31, 0.89) (p=0.016) and reduced the risk of MI by 42% (38 events in the atorvastatin calcium group vs. 64 events in the placebo group), HR 0.58, 95.1% CI (0.39, 0.86) (p=0.007). There was no significant difference between the treatment groups for angina, revascularization procedures, and acute CHD death.

There were 61 deaths in the atorvastatin calcium group vs. 82 deaths in the placebo group (HR 0.73, p=0.059).

Figure 2: Effect of Atorvastatin Calcium 10 mg/day on Time to Occurrence of Major Cardiovascular Event (myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke) in CARDS



In the Treating to New Targets Study (TNT), the effect of atorvastatin calcium 80 mg/day vs. atorvastatin calcium 10 mg/day on the reduction in cardiovascular events was assessed in 10,001 subjects (94% white, 81% male, 38% ≥65 years) with clinically evident coronary heart disease who had achieved a target LDL-C level <130 mg/dL after completing an 8-week, open-label, run-in period with atorvastatin calcium 10 mg/day. Subjects were randomly assigned to either 10 mg/day or 80 mg/day of atorvastatin calcium and followed for a median duration of 4.9 years. The primary endpoint was the time-to-first occurrence of any of the following major cardiovascular events (MCVE): death due to CHD, non-fatal myocardial infarction, resuscitated cardiac arrest, and fatal and non-fatal stroke. The mean LDL-C, TC, TG, non-HDL, and HDL cholesterol levels at 12 weeks were 73, 145, 128, 98, and 47 mg/dL during treatment with 80 mg of atorvastatin calcium and 99, 177, 152, 129, and 48 mg/dL during treatment with 10 mg of atorvastatin calcium.

Treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of MCVE (434 events in the 80 mg/day group vs. 548 events in the 10 mg/day group) with a relative risk reduction of 22%, HR 0.78, 95% CI (0.69, 0.89), p=0.0002 (see **Figure 3** and **Table 5**). The overall risk reduction was consistent regardless of age (<65, ≥65) or gender.

Figure 3: Effect of Atorvastatin Calcium 80 mg/ day vs. 10 mg/day on Time to Occurrence of Major Cardiovascular Events (TNT)

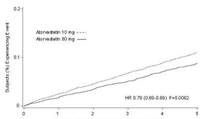


TABLE 5. Overview of Efficacy Results in TNT

Endpoint	Atorvastatin 10 mg (N=5006)		Atorvastatin 80 mg (N=4995)		HR[a] (95%CI)
	n	(%)	n	(%)	
PRIMARY ENDPOINT					
First major cardiovascular endpoint	548	(10.9)	434	(8.7)	0.78 (0.69, 0.89)
Components of the Primary Endpoint					
CHD death	127	(2.5)	101	(2)	0.80 (0.61, 1.03)
Non-fatal, non-procedure related MI	308	(6.2)	243	(4.9)	0.78 (0.66, 0.93)
Resuscitated cardiac arrest	26	(0.5)	25	(0.5)	0.96 (0.56, 1.67)
Stroke (fatal and non-fatal)	155	(3.1)	117	(2.3)	0.75 (0.59, 0.96)
SECONDARY ENDPOINTS					
First CHF with hospitalization	164	(3.3)	122	(2.4)	0.74 (0.59, 0.94)
First PVD endpoint	282	(5.6)	275	(5.5)	0.97 (0.83, 1.15)
First CABG or other coronary revascularization procedure[b]	904	(18.1)	667	(13.4)	0.72 (0.65, 0.80)
First documented angina endpoint[b]	615	(12.3)	545	(10.9)	0.88 (0.79, 0.99)
All-cause mortality	282	(5.6)	284	(5.7)	1.01 (0.85, 1.19)
Components of All-Cause Mortality					
Cardiovascular death	155	(3.1)	126	(2.5)	0.81 (0.64, 1.03)
Noncardiovascular death	127	(2.5)	158	(3.2)	1.25 (0.99, 1.57)
Cancer death	75	(1.5)	85	(1.7)	1.13 (0.83, 1.55)
Other non-CV death	43	(0.9)	58	(1.2)	1.35 (0.91, 2)
Suicide, homicide, and other traumatic non CV death	9	(0.2)	15	(0.3)	1.67 (0.73, 3.82)

a) Atorvastatin 80 mg: atorvastatin 10 mg
b) Component of other secondary endpoints
Secondary endpoints not included in primary endpoint

HR=hazard ratio; CHD=coronary heart disease; CI=confidence interval; MI=myocardial infarction; CHF=congestive heart failure; CV=cardiovascular; PVD=peripheral vascular disease; CABG=coronary artery bypass graft
Confidence intervals for the Secondary Endpoints were not adjusted for multiple comparisons

Of the events that comprised the primary efficacy endpoint, treatment with atorvastatin calcium 80 mg/ day significantly reduced the rate of non-fatal, non-procedure related MI and fatal and non-fatal stroke, but not CHD death or resuscitated cardiac arrest (**Table 5**). Of the predefined secondary endpoints, treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of coronary revascularization, angina, and hospitalization for heart failure, but not peripheral vascular disease. The reduction in the rate of CHF with hospitalization was only observed in the 8% of patients with a prior history of CHF.

There was no significant difference between the treatment groups for all-cause mortality (**Table 5**). The proportions of subjects who experienced cardiovascular death, including the components of CHD death and fatal stroke, were numerically smaller in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group. The proportions of subjects who experienced noncardiovascular death were numerically larger in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group.

In the Incremental Decrease in Endpoints Through Aggressive Lipid Lowering Study (IDEAL), treatment with atorvastatin calcium 80 mg/day was compared to treatment with simvastatin 20 to 40 mg/day in 8,888 subjects up to 80 years of age with a history of CHD to assess whether reduction in CV risk could be achieved. Patients were mainly male (81%), white (99%) with an average age of 61.7 years, and an average LDL-C of 121.5 mg/dL at randomization; 76% were on statin therapy. In this prospective, randomized, open-label, blinded endpoint (PROBE) trial with no run-in period, subjects were followed for a median duration of 4.8 years. The mean LDL-C, TC, TG, HDL, and non-HDL cholesterol levels at Week 12 were 78, 145, 115, 45, and 100 mg/dL during treatment with 80 mg of atorvastatin calcium and 105, 179, 142, 47, and 132 mg/dL during treatment with 20 to 40 mg of simvastatin.

There was no significant difference between the treatment groups for the primary endpoint, the rate of first major coronary event (fatal CHD, non-fatal MI, and resuscitated cardiac arrest): 411 (9.3%) in the atorvastatin calcium 80 mg/day group vs. 463 (10.4%) in the simvastatin 20 to 40 mg/day group, HR 0.89, 95% CI (0.78, 1.01), p=0.07.

There were no significant differences between the treatment groups for all-cause mortality: 366 (8.2%) in the atorvastatin calcium 80 mg/day group vs. 374 (8.4%) in the simvastatin 20 to 40 mg/day group. The proportions of subjects who experienced CV or non-CV death were similar for the atorvastatin calcium 80 mg group and the simvastatin 20 to 40 mg group.

14.2 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia *(Fredrickson* Types IIa and IIb)
Atorvastatin calcium reduces total-C, LDL-C, VLDL-C, apo B, and TG, and increases HDL-C in patients with hyperlipidemia and mixed dyslipidemia. Therapeutic response is seen within 2 weeks, and maximum response is usually achieved within 4 weeks and maintained during chronic therapy.

Atorvastatin calcium is effective in a wide variety of patient populations with hyperlipidemia, with and without hypertriglyceridemia, in men and women, and in the elderly.

In two multicenter, placebo-controlled, dose-response studies in patients with hyperlipidemia, atorvastatin calcium given as a single dose over 6 weeks, significantly reduced total-C, LDL-C, apo B, and TG. (Pooled results are provided in **Table 6**.)

TABLE 6. Dose Response in Patients With Primary Hyperlipidemia (Adjusted Mean % Change From Baseline)[a]

Dose	N	TC	LDL-C	Apo B	TG	HDL-C	Non-HDL-C/ HDL-C
Placebo	21	4	4	3	10	-3	7
10	22	-29	-39	-32	-19	6	-34
20	20	-33	-43	-35	-26	9	-41
40	21	-37	-50	-42	-29	6	-45
80	23	-45	-60	-50	-37	5	-53

a) Results are pooled from 2 dose-response studies.

In patients with *Fredrickson* Types IIa and IIb hyperlipoproteinemia pooled from 24 controlled trials, the median (25th and 75th percentile) percent changes from baseline in HDL-C for atorvastatin calcium 10, 20, 40, and 80 mg were 6.4 (-1.4, 14), 8.7 (0, 17), 7.8 (0, 16), and 5.1 (-2.7, 15), respectively. Additionally, analysis of the pooled data demonstrated consistent and significant decreases in total-C, LDL-C, TG, total-C/HDL-C, and LDL-C/HDL-C.

In three multicenter, double-blind studies in patients with hyperlipidemia, atorvastatin calcium was compared to other statins. After randomization, patients were treated for 16 weeks with either atorvastatin calcium 10 mg per day or a fixed dose of the comparative agent (**Table 7**).

TABLE 7. Mean Percentage Change From Baseline at Endpoint (Double-Blind, Randomized, Active-Controlled Trials)

Treatment (Daily Dose)	N	Total -C	LDL -C	Apo B	TG	HDL -C	Non-HDL-C/ HDL-C
Study 1							
Atorvastatin calcium 10 mg	707	-27*	-36*	-28*	-17*	7	-37*
Lovastatin 20 mg	191	-19	-27	-20	-6	7	-28
95% CI for Diff[a]		-9.2, -6.5	-10.7, -7.1	-10, -6.5	-15.2, -7.1	-1.7, 2	-11.1, -7.1
Study 2							
Atorvastatin calcium 10 mg	222	-25*	-35*	-27*	-17*	6	-36*
Pravastatin 20 mg	77	-17	-23	-17	-9	8	-28
95% CI for Diff[a]		-10.8, -6.1	-14.5, -8.2	-13.4, -7.4	-14.1, -0.7	-4.9, 1.6	-11.5, -4.1
Study 3							
Atorvastatin calcium 10 mg	132	-29*	-37*	-34*	-23*	7	-39*
Simvastatin 10 mg	45	-24	-30	-30	-15	7	-33
95% CI for Diff[a]		-8.7, -2.7	-10.1, -2.6	-8, -1.1	-15.1, -0.7	-4.3, 3.9	-9.6, -1.9

a) A negative value for the 95% CI for the difference between treatments favors atorvastatin calcium for all except HDL-C, for which a positive value favors atorvastatin calcium. If the range does not include 0, this indicates a statistically significant difference.
b) Significantly different from lovastatin, ANCOVA, p ≤0.05
c) Significantly different from pravastatin, ANCOVA, p ≤0.05
d) Significantly different from simvastatin, ANCOVA, p ≤0.05

The impact on clinical outcomes of the differences in lipid-altering effects between treatments shown in **Table 7** is not known. **Table 7** does not contain data comparing the effects of atorvastatin calcium 10 mg and higher doses of lovastatin, pravastatin, and simvastatin. The drugs compared in the studies summarized in the table are not necessarily interchangeable.

14.3 Hypertriglyceridemia *(Fredrickson* Type IV)
The response to atorvastatin calcium in 64 patients with isolated hypertriglyceridemia treated across several clinical trials is shown in the table below (**Table 8**). For the atorvastatin calcium-treated patients, median (min, max) baseline TG level was 565 (267 to 1502).

TABLE 8. Combined Patients With Isolated Elevated TG: Median (min, max) Percentage Change From Baseline

	Placebo (N=12)	Atorvastatin Calcium 10 mg (N=37)	Atorvastatin Calcium 20 mg (N=19)	Atorvastatin Calcium 80 mg (N=14)
Triglycerides	-12.4 (-36.6, 82.7)	-41 (-76.2, 49.4)	-38.7 (-62.7, 29.5)	-51.8 (-82.8, 41.3)
Total-C	-2.3 (-15.5, 24.4)	-28.2 (-44.9, -6.8)	-34.9 (-49.6, -15.2)	-44.4 (-63.5, -3.8)
LDL-C	3.6 (-31.3, 31.6)	-26.5 (-57.7, 9.8)	-30.4 (-53.9, 0.3)	-40.5 (-60.6, -13.8)
HDL-C	3.8 (-18.6, 13.4)	13.8 (-9.7, 61.5)	11 (-3.2, 25.2)	7.5 (-10.8, 37.2)
VLDL-C	-1 (-31.9, 53.2)	-48.8 (-85.8, 57.3)	-44.6 (-62.2, -10.8)	-62 (-88.2, 37.6)
non-HDL-C	-2.8 (-17.6, 30)	-33 (-52.1, -13.3)	-42.7 (-53.7, -17.4)	-51.5 (-72.9, -4.3)

14.4 Dysbetalipoproteinemia *(Fredrickson* Type III)
The results of an open-label crossover study of 16 patients (genotypes: 14 apo E2/E2 and 2 apo E3/E2) with dysbetalipoproteinemia *(Fredrickson* Type III) are shown in the table below (**Table 9**).

TABLE 9. Open-Label Crossover Study of 16 Patients With Dysbetalipoproteinemia (*Fredrickson* Type III)

	Median (min, max) at Baseline (mg/dL)	Median % Change (min, max)	
		Atorvastatin Calcium 10 mg	Atorvastatin Calcium 80 mg
Total-C	442 (225, 1320)	-37 (-85, 17)	-58 (-90, -31)
Triglycerides	678 (273, 5990)	-39 (-92, -8)	-53 (-95, -30)
IDL-C VLDL-C	215 (111, 613)	-32 (-76, 9)	-63 (-90, -8)
non-HDL-C	411 (218, 1272)	-43 (-87, -19)	-64 (-92, -36)

14.5 Homozygous Familial Hypercholesterolemia
In a study without a concurrent control group, 29 patients ages 6 to 37 years with homozygous FH received maximum daily doses of 20 to 80 mg of atorvastatin calcium. The mean LDL-C reduction in this study was 18%. Twenty-five patients with a reduction in LDL-C had a mean response of 20% (range of 7% to 53%, median of 24%); the remaining 4 patients had 7% to 24% increases in LDL-C. Five of the 29 patients had absent LDL-receptor function. Of these, 2 patients also had a portacaval shunt and had no significant reduction in LDL-C. The remaining 3 receptor-negative patients had a mean LDL-C reduction of 22%.

14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
In a double-blind, placebo-controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10 to 17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolemia (FH) or severe hypercholesterolemia, were randomized to atorvastatin calcium (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin calcium for 26 weeks. Inclusion in the study required 1) a baseline LDL-C level ≥ 190 mg/dL or 2) a baseline LDL-C level ≥ 160 mg/dL and positive family history of FH or documented premature cardiovascular disease in a first or second-degree relative. The mean baseline LDL-C value was 218.6 mg/dL (range: 138.5 to 385 mg/dL) in the atorvastatin calcium group compared to 230 mg/dL (range: 160 to 324.5 mg/dL) in the placebo group. The dosage of atorvastatin calcium (once daily) was 10 mg for the first 4 weeks and uptitrated to 20 mg if the LDL-C level was > 130 mg/dL. The number of atorvastatin calcium-treated patients who required uptitration to 20 mg after Week 4 during the double-blind phase was 80 (57.1%).

Atorvastatin calcium significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26-week double-blind phase (see **Table 10**).

TABLE 10. Lipid-altering Effects of Atorvastatin Calcium in Adolescent Boys and Girls with Heterozygous Familial Hypercholesterolemia or Severe Hypercholesterolemia (Mean Percentage Change From Baseline at Endpoint in Intention-to-Treat Population)

DOSAGE	N	Total -C	LDL -C	HDL -C	TG	Apolipo-protein B
Placebo	47	-1.5	-0.4	-1.9	1	0.7
Atorvastatin calcium	140	-31.4	-39.6	2.8	-12	-34

The mean achieved LDL-C value was 130.7 mg/dL (range: 70 to 242 mg/dL) in the atorvastatin calcium group compared to 228.5 mg/dL (range: 152 to 385 mg/ dL) in the placebo group during the 26-week double-blind phase.

The safety and efficacy of doses above 20 mg have not been studied in controlled trials in children. The long-term efficacy of atorvastatin calcium therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

15. REFERENCES
[1] National Cholesterol Education Program (NCEP): Highlights of the Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents, *Pediatrics*. 89(3):495–501. 1992.

16. HOW SUPPLIED/STORAGE AND HANDLING
Atorvastatin calcium tablets are supplied as follows:

10 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 10" on one side. Bottles contain desiccant.
NDC 0781-5381-31, bottle of 30 tablets
NDC 0781-5381-92, bottle of 90 tablets
NDC 0781-5381-01, bottle of 100 tablets
NDC 0781-5381-10, bottle of 1000 tablets
NDC 0781-5381-34, bottle of 3000 tablets

20 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 20" on one side. Bottles contain desiccant.
NDC 0781-5382-31, bottle of 30 tablets
NDC 0781-5382-92, bottle of 90 tablets
NDC 0781-5382-01, bottle of 100 tablets
NDC 0781-5382-10, bottle of 1000 tablets
NDC 0781-5382-34, bottle of 3000 tablets

40 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 40" on one side. Bottles contain desiccant.
NDC 0781-5384-31, bottle of 30 tablets
NDC 0781-5384-92, bottle of 90 tablets
NDC 0781-5384-01, bottle of 100 tablets
NDC 0781-5384-10, bottle of 1000 tablets
NDC 0781-5384-22, bottle of 2000 tablets

80 mg, light yellow, dappled, glossy, oval biconvex film-coated tablets, debossed with "HLA 80" on one side. Bottles contain desiccant.
NDC 0781-5388-31, bottle of 30 tablets
NDC 0781-5388-92, bottle of 90 tablets
NDC 0781-5388-01, bottle of 100 tablets
NDC 0781-5388-10, bottle of 1000 tablets

Storage
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

17. PATIENT COUNSELING INFORMATION
Patients taking atorvastatin calcium tablets should be advised that cholesterol is a chronic condition and they should adhere to their medication along with their National Cholesterol Education Program (NCEP)-recommended diet, a regular exercise program as appropriate, and periodic testing of a fasting lipid panel to determine goal attainment.

Patients should be advised about substances they should not take concomitantly with atorvastatin [see **WARNINGS AND PRECAUTIONS (5.1)**]**. Patients should also be advised to inform other healthcare professionals prescribing a new medication that they are taking atorvastatin calcium tablets.**

17.1 Muscle Pain
All patients starting therapy with atorvastatin calcium tablets should be advised of the risk of myopathy and told to report promptly any unexplained muscle pain, tenderness, or weakness. The risk of this occurring is increased when taking certain types of medication or consuming larger quantities (>1 liter) of grapefruit juice. They should discuss all medication, both prescription and over the counter, with their healthcare professional.

17.2 Liver Enzymes
It is recommended that liver enzyme tests be performed before the initiation of atorvastatin calcium tablets and if signs or symptoms of liver injury occur. All patients treated with atorvastatin calcium tablets should be advised to report promptly any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

17.3 Pregnancy
Women of childbearing age should be advised to use an effective method of birth control to prevent pregnancy while using atorvastatin calcium tablets. Discuss future pregnancy plans with your patients, and discuss when to stop atorvastatin calcium tablets if they are trying to conceive. Patients should be advised that if they become pregnant, they should stop taking atorvastatin calcium tablets and call their healthcare professional.

17.4 Breastfeeding
Women who are breastfeeding should be advised to not use atorvastatin calcium tablets. Patients who have a lipid disorder and are breastfeeding, should be advised to discuss the options with their healthcare professional.

PATIENT INFORMATION
Atorvastatin Calcium Tablets

Read the Patient Information that comes with atorvastatin calcium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about atorvastatin calcium tablets, ask your doctor or pharmacist.

What are Atorvastatin Calcium Tablets?
Atorvastatin calcium tablets are a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. Atorvastatin calcium tablets are for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

Atorvastatin calcium tablets can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:
- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

Atorvastatin calcium tablets can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:
- eye problems, kidney problems, smoking, or high blood pressure.

Atorvastatin calcium tablets start to work in about 2 weeks.

What is Cholesterol?
Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

Who Should Not Take Atorvastatin Calcium Tablets?
Do not take atorvastatin calcium tablets if you:
- are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you get pregnant, stop taking atorvastatin calcium tablets and call your doctor right away.
- are breast feeding. Atorvastatin calcium tablets can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to atorvastatin calcium tablets or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Atorvastatin calcium tablets have not been studied in children under 10 years of age.

Before You Start Atorvastatin Calcium Tablets
Tell your doctor if you:
- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with atorvastatin calcium tablets. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:
- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take.
Keep a list of them with you to show your doctor and pharmacist.

How Should I Take Atorvastatin Calcium Tablets?
- Take atorvastatin calcium tablets exactly as prescribed by your doctor. Do not change your dose or stop atorvastatin calc

PATIENT INFORMATION
Atorvastatin Calcium Tablets

Read the Patient Information that comes with atorvastatin calcium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about atorvastatin calcium tablets, ask your doctor or pharmacist.

What are Atorvastatin Calcium Tablets?
Atorvastatin calcium tablets are a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. Atorvastatin calcium tablets are for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

Atorvastatin calcium tablets can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:
- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

Atorvastatin calcium tablets can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:
- eye problems, kidney problems, smoking, or high blood pressure.

Atorvastatin calcium tablets start to work in about 2 weeks.

What is Cholesterol?
Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

Who Should Not Take Atorvastatin Calcium Tablets?
Do not take atorvastatin calcium tablets if you:
- are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you get pregnant, stop taking atorvastatin calcium tablets and call your doctor right away.
- are breast feeding**.** Atorvastatin calcium tablets can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to atorvastatin calcium tablets or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Atorvastatin calcium tablets have not been studied in children under 10 years of age.

Before You Start Atorvastatin Calcium Tablets
Tell your doctor if you:
- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with atorvastatin calcium tablets. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:
- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take.

Keep a list of them with you to show your doctor and pharmacist.

How Should I Take Atorvastatin Calcium Tablets?
- Take atorvastatin calcium tablets exactly as prescribed by your doctor. Do not change your dose or stop atorvastatin calcium tablets without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with atorvastatin calcium tablets. Your dose of atorvastatin calcium tablets may be changed based on these blood test results.
- Take atorvastatin calcium tablets each day at any time of day at about the same time each day. Atorvastatin calcium tablets can be taken with or without food. Don't break atorvastatin calcium tablets before taking.
- Your doctor should start you on a low-fat diet before giving you atorvastatin calcium tablets. Stay on this low-fat diet when you take atorvastatin calcium tablets.
- If you miss a dose of atorvastatin calcium tablets, take it as soon as you remember. Do not take atorvastatin calcium tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of atorvastatin calcium tablets at the same time.



- If you take too much atorvastatin calcium tablets or overdose, call your doctor or Poison Control Center right away. Or go to the nearest emergency room.

What Should I Avoid While Taking Atorvastatin Calcium Tablets?
- Talk to your doctor before you start any new medicines. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects.
- Do not get pregnant. If you get pregnant, stop taking atorvastatin calcium tablets right away and call your doctor.

What are the Possible Side Effects of Atorvastatin Calcium Tablets?

Atorvastatin calcium tablets can cause serious side effects. These side effects have happened only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or atorvastatin calcium tablets are stopped. These serious side effects include:

- **Muscle problems.** Atorvastatin calcium tablets can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with atorvastatin calcium tablets.
- **Liver problems.** Your doctor should do blood tests to check your liver before you start taking atorvastatin calcium tablets, and if you have symptoms of liver problems while you take atorvastatin calcium tablets. Call your doctor right away if you have the following symptoms of liver problems:
  - feel tired or weak
  - loss of appetite
  - upper belly pain
  - dark amber colored urine
  - yellowing of your skin or the whites of your eyes

Call your doctor right away if you have:
- muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual.
- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- nausea and vomiting.
- passing brown or dark-colored urine.
- you feel more tired than usual
- your skin and whites of your eyes get yellow.
- stomach pain.
- allergic skin reactions.

In clinical studies, patients reported the following common side effects while taking atorvastatin calcium tablets: diarrhea, upset stomach, muscle and joint pain, and alterations in some laboratory blood tests.

The following additional side effects have been reported with atorvastatin calcium tablets:
tiredness, tendon problems, memory loss, and confusion.

Talk to your doctor or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of atorvastatin calcium tablets. Ask your doctor or pharmacist for a complete list.

How do I store Atorvastatin Calcium Tablets?

- Store atorvastatin calcium tablets at room temperature 68° to 77°F (20° to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep atorvastatin calcium tablets and all medicines out of the reach of children.** Be sure that if you throw medicine away, it is out of the reach of children.

General Information About Atorvastatin Calcium Tablets
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use atorvastatin calcium tablets for a condition for which it was not prescribed. Do not give atorvastatin calcium tablets to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about atorvastatin calcium tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about atorvastatin calcium tablets that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the Ingredients in Atorvastatin Calcium Tablets?
Active Ingredient: atorvastatin calcium
Inactive Ingredients: carboxymethylcellulose sodium, ferric oxide yellow, glycerin, magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate, talc, tromethamine.

℞ only
Manufactured in Slovenia by Lek Pharmaceuticals d.d,
for Sandoz Inc., Princeton, NJ 08540

Revised: March 2012

46082127

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

LABELING REVIEWS

*****This Approval Summary supersedes the AP summary dated 6/10/11 in DARRTS*****

LABELING APPROVAL SUMMARY #2

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 077575 Date of Submission: March 23, 2012 & May 31, 2011

Applicant's Name: Sandoz Inc.

Established Name: Atorvastatin Calcium tablets 10 mg, 20 mg, 40 mg, and 80 mg

---

REMS required?

MedGuides and/or PPIs (505-1(e))	☐ Yes	☒ No
Communication plan (505-1(e))	☐ Yes	☒ No
Elements to assure safe use (ETASU) (505-1(f)(3))	☐ Yes	☒ No
Implementation system if certain ETASU (505-1(f)(4))	☐ Yes	☒ No
Timetable for assessment (505-1(d))	☐ Yes	☒ No

ANDA REMS acceptable?
☐ Yes ☐ No ☒ n/a

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? Electronic Submission

Container Labels (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets):
Final printed labels acceptable in 5/31/11 e-submission

Professional Package Insert Labeling: Final printed labeling acceptable in 3/23/2012 e-submission

Patient Information Sheet: Final printed labeling acceptable in 3/23/2012 e-submission

Revisions needed before full approval: No

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Lipitor

NDA Number: 020702

NDA Drug Name: Lipitor

NDA Firm: Pfizer Inc.

Date of Approval of NDA Insert and supplement #: 020702/S-060; approved 2/28/2012.

Was this approval based upon an OGD labeling guidance? No

Note: The applicant is using an (b) (4) form while the RLD has the trihydrate form.

NOTE TO CHEMIST: applicant use the (b) (4) product with the RLD use the trihydrate product please let me know if there is a difference in the safety and efficacy of the different forms.

I emailed Gil Kang on December 8, 2010 to verify the (b) (4) form vs. trihydrate form.

FOR THE RECORD: (parts of review based on B. Weitzman's LBL TA SUM)
Please note that the last 2 review cycles were completed by labeling reviewer, Thuyanh Vu. Parts of this review were taken from the review dated 6/10/2011 in DARRTS.

1. **MODEL LABELING:** This review was based on the labeling of the RLD, Lipitor® (atorvastatin calcium) Tablets, NDA 020702/S-060; approved February 28, 2012.
   The PI is now in PLR format (see supplement 056, approved 6/17/09).

Container



2. **MEDWATCH: No new reports since last labeling approved (checked 4/19/2012)**
   Lipitor (atorvastatin calcium) Tablets March 2009
   Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER) -- March 2009 and February 2012

3. **PATENTS/EXCLUSIVITIES: [Patent amendment dated 6/15/10]**

Patent No	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
4681893	Sep. 24, 2009 PED. Mar. 24, 2010	U-161	method of treating hypercholesterolemia METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS IN A PATIENT	PIII	Same As
5273995	Dec 28, 2010 ped jun 28, 2011	u-162	METHOD OF USE TO INHIBIT CHOLESTEROL SYNTHESIS IN A HUMAN SUFFERING FROM HYPERCHOLESTEROLEMIA	PIII	Same As
5686104	Nov 11, 2014 ped May 11, 2015	U-213	METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS AND TREATING HYPERCHOLESTEROLEMIA AND METHOD FOR TREATING HYPERLIPIDEMIA	PIV	Same As
	Jul 8, 2016 ped			PIV	Same As

5969156	Jan 8, 2017				
6126971	Jan 19, 2013 ped July 19, 2013	—		PIV	Same As
RE 40667	Jun 28, 2011*PED	U-162	Method of use to inhibit choletestrol synthesis in a human suffering from hypercholesterolemia	PIII	Same As

According to M. Holovac's email dated 12/6/10: Pfizer did NOT list the 7,790,197 patent yet.

PATENT AMENDMENT dated 4/18/2012:

The firm filed a PIV certification to all of the patents currently listed in the Orange Book. The firm also addressed certification to another patent that is not listed in the Orange Book.

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

See email regarding the certification to Patent No. 8026376 not listed in the OB.

From: Holovac, Mary Ann
Sent: Wednesday, April 18, 2012 9:37 AM
To: Turner, Betty
Cc: Shimer, Martin
Subject: RE: PATENT LISTING

Hi Betty,

If it is not listed (which it isn't) nobody needs to certify to it. As the patent issued last Sept they missed the 30 day window for it to be considered timely filed so anyone already in house won't need to cert. Pfizer is always on top of getting their patents to me so I'm sure it isn't "lost". The ANDA firm may have been doing serial certifications in an abundance of caution in case it was listed but they can't cert to a not listed patent.

Mary Ann

From: Turner, Betty
Sent: Wednesday, April 18, 2012 9:13 AM
To: Holovac, Mary Ann
Subject: PATENT LISTING

Hi Mary Ann,

I was working on a review for ANDA 77575 Atorvastatin Calcium by Sandoz and found a Patent not listed in the OB. The firm submitted a Patent Amendment which included Patent No. 8026376 which expires May 13, 2027, PEDS Nov 23, 2027. The owner of the Patent is Pfizer Inc. The firm filed a PIV for the Patent. Just wanted to verify that this is ok for me to include in my review. Also, if this is listed in the OB, then all of the firms will have to certify to this patent. Atorvastatin is up for approval the end of May, so I may have to ask the firms to certify to this Patent.

Thanks,

Betty

4. MANUFACTURING FACILITY OF FINISHED DOSAGE FORM:
by Lek Pharmaceuticals d.d. at Verovskova 5, 1526 Ljubljana,Slovenia [Vol. A1.]

Lek transfer of ownership to Sandoz per D. Doan's acknowledgement dated 8/16/10.

5. INACTIVE INGREDIENTS:

The description of the inactive ingredients in the insert labeling appears accurate according to the composition statement. [Vol. A1.1 pg. 106 and Vol. A1.2 pg. 532.] Atorvastatin Calcium Tablets contain atorvastatin and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine. The 80 mg give (b) (4) per tab elemental with ferric oxide being (b) (4) mg/tab

Per Chemist review #3 all of the tablets have less than (b) (6) mg ferric oxide per tab, thus all tabs have less than 5 mg elemental iron per tab.

6. FINISHED DOSAGE FORM:

NDA: LIPITOR® (atorvastatin calcium) is supplied as white, elliptical, film-coated tablets of atorvastatin calcium containing 10, 20, 40 and 80 mg atorvastatin.
10 mg tablets: coded "PD 155" on one side and "10" on the other.
Bottles of 90 and 5000 and 10 x 10 unit dose blisters
20 mg tablets: coded "PD 156" on one side and "20" on the other. Bottles of 90 and 5000 and 10 x 10 unit dose blisters.
40 mg tablets: coded "PD 157" on one side and "40" on the other. Bottles of 90 and 500
80 mg tablets: coded "PD 158" on one side and "80" on the other. Bottles of 90 and 500

ANDA:
10 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 10" on one side
20 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 20" on one side
40 mg tablets Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 40" on one side
80 mg tablets Light yellow, dappled, glossy, **oval** biconvex film-coated tablet, debossed with "HLA 80" on one side

7. CONTAINER/CLOSURE: Section XIII of 5/31/11 e-submission

Product Strength	Fill Size (tablets)	Bottle (mL)	Cap (dimensions)	(b) (4)
10 mg and 20 mg	30s, 90s, 100s	(b) (4)	(b) (4)	

Product Strength	Fill Size (tablets)	Bottle (mL)	Cap (dimensions)	(b) (4)
	1000	(b) (4)	(b) (4)	
	3000			
40 mg	30s, 90s, 100s			
	1000			
	2000			
80 mg	30s, 90s, 100s			
	1000			

In AF 5/31/11 e-submission, firm confirms that they are not launching the (b) (4)

(b) (4)

9. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON:

RLD: store at 25C(77F); excursions permitted to 15-30C (59-86F) [See USP CRT]. Keep tightly closed (protect from moisture). Protect from light.

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. (carton label)

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container. (container label)

10. DISPENSING STATEMENTS COMPARISON:

NDA – Dispense in Well closed containers (USP)

ANDA – Dispense in a tight, light-resistant container. (container label)

USP – The DS is pending compendial

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at room temperature.

11. BIOAVAILABILITY/BIOEQUIVALENCE: the firm uses the (b) (4) form rather than the trihydrate

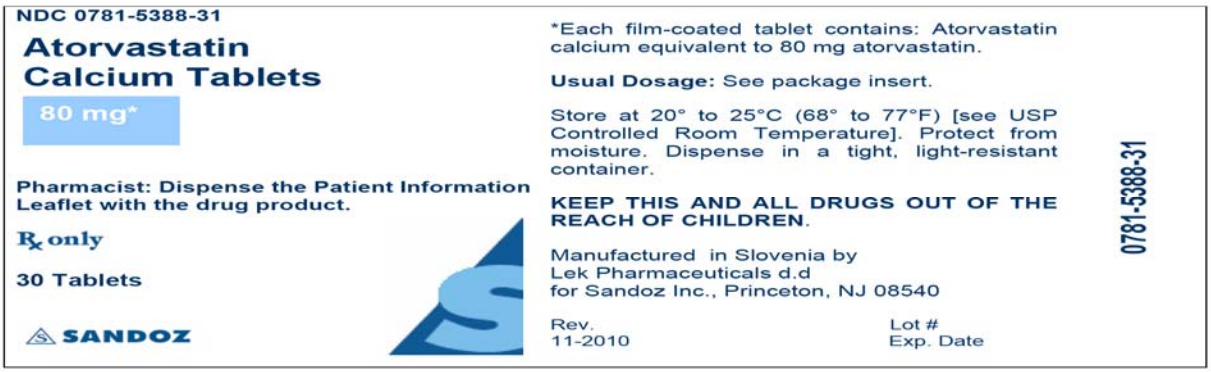
As of December 8, 2010, DBE has no further questions per G. Li's review dated 5/7/2010.

12. CONTAINER LABELS:

The following container labels were submitted in draft in the amendment date11/22/2010.









Final printed labels were submitted in the May 31, 2011 amendment.

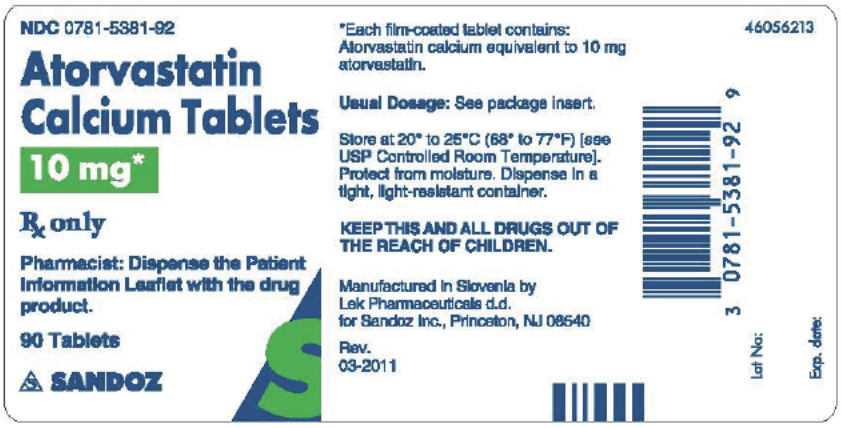
Date of Review: April 19, 2012 **Date of Submission: March 23, 2012 and May 31, 2011**

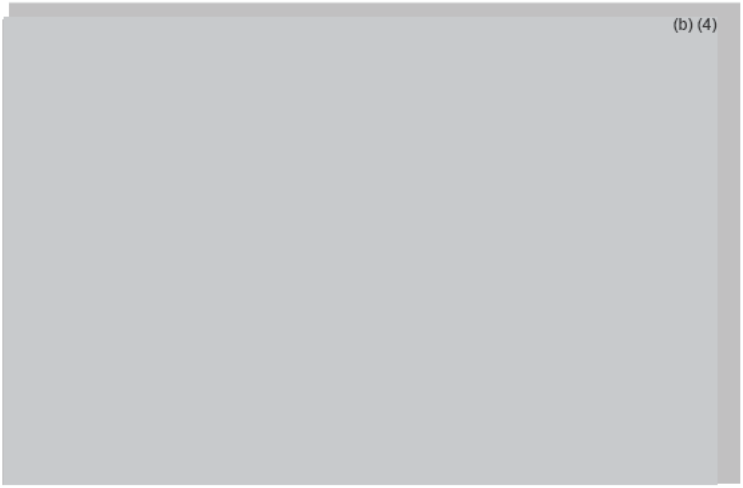
Primary Reviewer: Betty Turner **Team Leader: Ruby (Chi-Ann) Wu**

ANDA 077575 **AP Summary #2**


NDC 0781-5381-31
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056212
3 0781-5381-31 8
Lot No:
Exp. date:

(b) (4)


NDC 0781-5381-92
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056213
3 0781-5381-92 9
Lot No:
Exp. date:


(b) (4)


NDC 0781-5381-01
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
100 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056214
3 0781-5381-01 1
Lot No:
Exp. date:

(b) (4)

NDC 0781-5381-10

Atorvastatin Calcium Tablets

10 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
10 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5381-10 3

Lot No:

Exp. date:

46056215

(b) (4)

NDC 0781-5381-34

Atorvastatin Calcium Tablets

10 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

3000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
10 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5381-34 9

Lot No:

Exp. date:

46056216

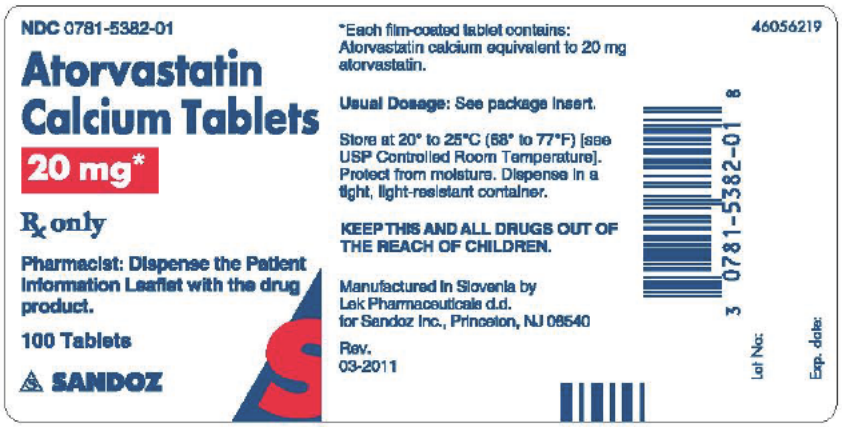
(b) (4)


NDC 0781-5382-31
Atorvastatin Calcium Tablets
20 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 20 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056217
3 0781-5382-31 5
Lot No:
Exp. date:

(b) (4)


NDC 0781-5382-92
Atorvastatin Calcium Tablets
20 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 20 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056218
3 0781-5382-92 6
Lot No:
Exp. date:

(b) (4)



(b) (4)

Additional demands.

NDC 0781-5382-10

Atorvastatin Calcium Tablets

20 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
20 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5382-10 0

Lot No:

Exp. date:

46056220

(b) (4)

NDC 0781-5382-34

Atorvastatin Calcium Tablets

20 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

3000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
20 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5382-34 6

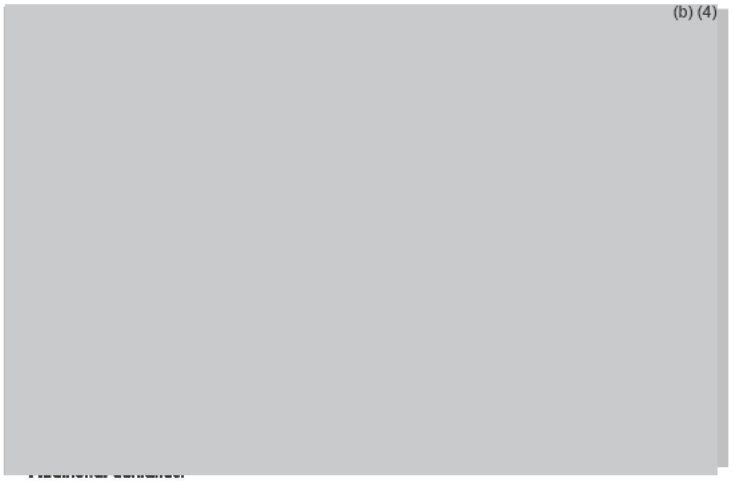
46056221

Lot No:

Exp. date:

(b) (4)


NDC 0781-5384-31
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev.
03-2011
46056222
3 0781-5384-31 9
Lot No:
Exp. date:


(b) (4)


NDC 0781-5384-92
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056223
3 0781-5384-92 0
Lot No:
Exp. date:


(b) (4)


NDC 0781-5384-01
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
100 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056224
3 0781-5384-01 2
Lot No:
Exp. date:


(b) (4)

NDC 0781-5384-10

Atorvastatin Calcium Tablets

40 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
40 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5384-10 4

46056225

Lot No:

Exp. date:

(b) (4)

NDC 0781-5384-22

Atorvastatin Calcium Tablets

40 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

2000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
40 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5384-22 7

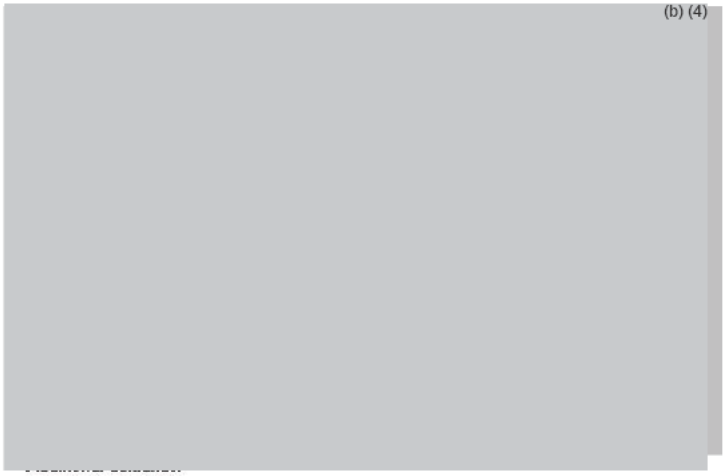
46056226

Lot No:

Exp. date:

(b) (4)


NDC 0781-5388-31
Atorvastatin Calcium Tablets
80 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev.
03-2011
46056227
3 0781-5388-31 7
Lot No:
Exp. date:


(b) (4)

NDC 0781-5388-92

Atorvastatin Calcium Tablets

80 mg*

℞ only

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

90 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

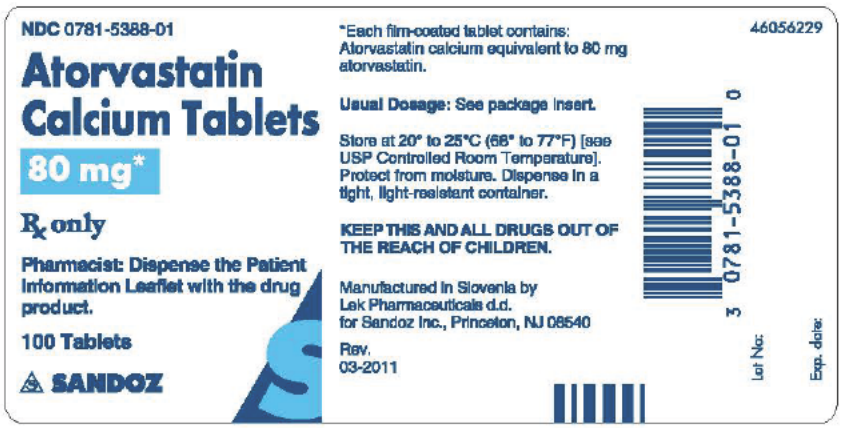
46056228

3 0781-5388-92 8

Lot No:

Exp. date:

(b) (4)


NDC 0781-5388-01
Atorvastatin Calcium Tablets
80 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
100 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056229
3 0781-5388-01 0
Lot No:
Exp. date:


(b) (4)

NDC 0781-5388-10

Atorvastatin Calcium Tablets

80 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5388-10 2

46056230

Lot No:

Exp. date:

(b) (4)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Atorvastatin Calcium Tablets safely and effectively. See full prescribing information for Atorvastatin Calcium Tablets.

Atorvastatin Calcium Tablets for oral administration
Initial U.S. Approval: 1996

----------RECENT MAJOR CHANGES----------

Drug Interactions (7)	02/2012

----------INDICATIONS AND USAGE----------

Atorvastatin calcium tablet is an inhibitor of HMG-CoA reductase (statin) indicated as an adjunct therapy to diet to:

- Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without CHD, but with multiple risk factors (1.1).
- Reduce the risk of MI and stroke in patients with type 2 diabetes without CHD, but with multiple risk factors (1.1).
- Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in patients with CHD (1.1).
- Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (1.2).
- Reduce elevated TG in patients with hypertriglyceridemia and primary dysbetalipoproteinemia (1.2).
- Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) (1.2).
- Reduce elevated total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy (1.2).

Limitations of Use

Atorvastatin calcium tablets have not been studied in *Fredrickson* Types I and V dyslipidemias.

----------DOSAGE AND ADMINISTRATION----------

Dose range: 10 to 80 mg once daily (2.1).
Recommended start dose: 10 or 20 mg once daily (2.1).
Patients requiring large LDL-C reduction (>45%) may start at 40 mg once daily (2.1).
Pediatric starting dose: 10 mg once daily; maximum recommended dose: 20 mg once daily (2.2).

----------DOSAGE FORMS AND STRENGTHS----------

10, 20, 40, and 80 mg tablets (3).

----------CONTRAINDICATIONS----------

Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels (4.1).
Women who are pregnant or may become pregnant (4.3).
Nursing mothers (4.4).
Hypersensitivity to any component of this medication (4.2).

----------WARNINGS AND PRECAUTIONS----------

Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase when higher doses are used concomitantly with cyclosporine and strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, HIV protease inhibitors). Predisposing factors include advanced age (> 65), uncontrolled hypothyroidism, and renal impairment. Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported. In cases of myopathy or rhabdomyolysis, therapy should be temporarily withheld or discontinued (5.1, 8.5).

Liver enzyme abnormalities: Persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter (5.2).

A higher incidence of hemorrhagic stroke was seen in patients without CHD but with stroke or TIA within the previous 6 months in the atorvastatin calcium 80 mg group vs. placebo (5.5).

----------ADVERSE REACTIONS----------

The most commonly reported adverse reactions (incidence ≥ 2%) in patients treated with atorvastatin calcium in placebo-controlled trials regardless of causality were: nasopharyngitis, arthralgia, diarrhea, pain in extremity, and urinary tract infection (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc., at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Drug Interactions Associated with Increased Risk of Myopathy/Rhabdomyolysis (2.6, 5.1, 7, 12.3)

Interacting Agents	Prescribing Recommendations
Cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir)	Avoid atorvastatin
HIV protease inhibitor (lopinavir plus ritonavir)	Use with caution and lowest dose necessary
Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir)	Do not exceed 20 mg atorvastatin daily
HIV protease inhibitor (nelfinavir)	Do not exceed 40 mg atorvastatin daily

- Other Lipid-Lowering Medications: Use with fibrate products or lipid-modifying doses (≥1 g/day) of niacin increases the risk of adverse skeletal muscle effects. Caution should be used when prescribing with atorvastatin calcium (7).
- Digoxin: Patients should be monitored appropriately (7.8).
- Oral Contraceptives: Values for norethindrone and ethinyl estradiol may be increased (7.9).
- Rifampin should be simultaneously co-administered with atorvastatin calcium (7.7).

----------USE IN SPECIFIC POPULATIONS----------

- Hepatic impairment: Plasma concentrations markedly increased in patients with chronic alcoholic liver disease (12.3).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2012

FULL PRESCRIBING INFORMATION CONTENTS*

1. INDICATIONS AND USAGE
   1.1 Prevention of Cardiovascular Disease
   1.2 Hyperlipidemia
   1.3 Limitations of Use
2. DOSAGE AND ADMINISTRATION
   2.1 Hyperlipidemia
   2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
   2.3 Homozygous Familial Hypercholesterolemia
   2.4 Concomitant Lipid-Lowering Therapy
   2.5 Dosage in Patients With Renal Impairment
   2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or Certain Protease Inhibitors
3. DOSAGE FORMS AND STRENGTHS
4. CONTRAINDICATIONS
   4.1 Active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels
   4.2 Hypersensitivity to any component of this medication
   4.3 Pregnancy
   4.4 Nursing mothers
5. WARNINGS AND PRECAUTIONS
   5.1 Skeletal Muscle
   5.2 Liver Dysfunction
   5.3 Endocrine Function
   5.4 CNS Toxicity
   5.5 Use in Patients with Recent Stroke or TIA
6. ADVERSE REACTIONS
   6.1 Clinical Trial Adverse Experiences
   6.2 Postmarketing Experience
   6.3 Pediatric Patients (ages 10 to 17 years)
7. DRUG INTERACTIONS
   7.1 Strong Inhibitors of Cytochrome P450 3A4
   Clarithromycin
   Combination of Protease Inhibitors
   Itraconazole
   7.2 Grapefruit Juice
   7.3 Cyclosporine
   7.4 Gemfibrozil
   7.5 Other Fibrates
   7.6 Niacin
   7.7 Rifampin or other Inducers of Cytochrome P450 3A4
   7.8 Digoxin
   7.9 Oral Contraceptives
   7.10 Warfarin
   7.11 Colchicine
8. USE IN SPECIFIC POPULATIONS
   8.1 Pregnancy
   8.2 Nursing Mothers
   8.3 Pediatric Use
   8.4 Geriatric Use
   8.5 Hepatic Impairment
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
   12.1 Mechanism of Action
   12.2 Pharmacodynamics
   12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
   13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
   14.1 Prevention of Cardiovascular Disease
   14.2 Hyperlipidemia and Mixed Dyslipidemia
   14.3 Hypertriglyceridemia
   14.4 Dysbetalipoproteinemia
   14.5 Homozygous Familial Hypercholesterolemia
   14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
   17.1 Muscle Pain
   17.2 Liver Enzymes
   17.3 Pregnancy
   17.4 Breastfeeding

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, atorvastatin calcium tablets can be started simultaneously with diet.

1.1 Prevention of Cardiovascular Disease

In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin calcium tablets are indicated to:

- Reduce the risk of myocardial infarction
- Reduce the risk of stroke
- Reduce the risk for revascularization procedures and angina

In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin calcium tablets are indicated to:

- Reduce the risk of myocardial infarction
- Reduce the risk of stroke

In patients with clinically evident coronary heart disease, atorvastatin calcium tablets are indicated to:

- Reduce the risk of non-fatal myocardial infarction
- Reduce the risk of fatal and non-fatal stroke
- Reduce the risk for revascularization procedures
- Reduce the risk of hospitalization for CHF
- Reduce the risk of angina

1.2 Hyperlipidemia

Atorvastatin calcium tablets are indicated:

- As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb);
- As an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV);
- For the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet;
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable;
- As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
  a. LDL-C remains ≥ 190 mg/dL or
  b. LDL-C remains ≥ 160 mg/dL and:
     - there is a positive family history of premature cardiovascular disease or
     - two or more other CVD risk factors are present in the pediatric patient

1.3 Limitations of Use

Atorvastatin calcium tablets have not been studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons (*Fredrickson* Types I and V).

2. DOSAGE AND ADMINISTRATION

2.1 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Types IIa and IIb)

The recommended starting dose of atorvastatin calcium tablets is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of atorvastatin calcium tablets is 10 to 80 mg once daily. Atorvastatin calcium tablets can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses of atorvastatin calcium tablets should be individualized according to patient characteristics such as goal of therapy and response (see current *NCEP Guidelines*). After initiation and/or upon titration of atorvastatin calcium tablets, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.

2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10 to 17 years of age)

The recommended starting dose of atorvastatin calcium tablets is 10 mg/day; the maximum recommended dose is 20 mg/day (doses greater than 20 mg have not been studied in this patient population). Dose should be individualized according to the recommended goal of therapy [see current *NCEP Pediatric Panel Guidelines*, **CLINICAL PHARMACOLOGY (12)**, and **INDICATIONS AND USAGE (1.2)**]. Adjustments should be made at intervals of 4 weeks or more.

2.3 Homozygous Familial Hypercholesterolemia

The dosage of atorvastatin calcium tablets in patients with homozygous FH is 10 to 80 mg daily. Atorvastatin calcium tablets should be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) in these patients or if such treatments are unavailable.

2.4 Concomitant Lipid-Lowering Therapy

Atorvastatin calcium tablets may be used with bile acid resins. The combination of HMG-CoA reductase inhibitors (statins) and fibrates should generally be used with caution [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), DRUG INTERACTIONS (7)**].

2.5 Dosage in Patients With Renal Impairment

Renal disease does not affect the plasma concentrations nor LDL-C reduction of atorvastatin calcium tablets; thus, dosage adjustment in patients with renal dysfunction is not necessary [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), CLINICAL PHARMACOLOGY, Pharmacokinetics (12.3)**].

2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or Certain Protease Inhibitors

In patients taking cyclosporine or the HIV protease inhibitors (tipranavir plus ritonavir) or the hepatitis C protease inhibitor (telaprevir), therapy with atorvastatin calcium tablets should be avoided. In patients with HIV taking lopinavir plus ritonavir, caution should be used when prescribing atorvastatin calcium tablets and the lowest dose necessary employed. In patients taking clarithromycin, itraconazole, or in patients with HIV taking a combination of saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, therapy with atorvastatin calcium tablets should be limited to 20 mg, and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin calcium tablets are employed. In patients with HIV taking nelfinavir, therapy with atorvastatin calcium tablets should be limited to 40 mg, and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin calcium tablets are employed [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), Drug Interactions (7)**].

3. DOSAGE FORMS AND STRENGTHS

Light yellow, dappled, glossy, round biconvex, film-coated tablets containing 10, 20, and 40 mg atorvastatin calcium.

Light yellow, dappled, glossy, oval biconvex, film-coated tablets containing 80 mg atorvastatin calcium.

4. CONTRAINDICATIONS

4.1 Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels

4.2 Hypersensitivity to any component of this medication

4.3 Pregnancy

Women who are pregnant or may become pregnant. Atorvastatin calcium may cause fetal harm when administered to a pregnant woman. Serum cholesterol and triglycerides increase during normal pregnancy, and cholesterol or cholesterol derivatives are essential for fetal development. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. There are no adequate and well-controlled studies of atorvastatin calcium use during pregnancy, however in rare reports, congenital anomalies were observed following intrauterine exposure to statins. In rat and rabbit animal reproduction studies, atorvastatin revealed no evidence of teratogenicity. ATORVASTATIN CALCIUM SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS. If the patient becomes pregnant while taking this drug, atorvastatin calcium should be discontinued immediately and the patient apprised of the potential hazard to the fetus [see **USE IN SPECIFIC POPULATIONS (8.1)**].

4.4 Nursing mothers

It is not known whether atorvastatin is excreted into human milk; however a small amount of another drug in this class does pass into breast milk. Because statins have the potential for serious adverse reactions in nursing infants, women who require atorvastatin calcium treatment should not breastfeed their infants [see **USE IN SPECIFIC POPULATIONS (8.3)**].

5. WARNINGS AND PRECAUTIONS

5.1 Skeletal Muscle

Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin calcium and with other drugs in this class. A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Such patients merit closer monitoring for skeletal muscle effects.

Atorvastatin, like other statins, occasionally causes myopathy, defined as muscle aches or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values >10 times ULN. The concomitant use of higher doses of atorvastatin with certain drugs such as cyclosporine and strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, and HIV protease inhibitors) increases the risk of myopathy/rhabdomyolysis.

Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. Atorvastatin calcium therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

The risk of myopathy during treatment with drugs in this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, erythromycin, clarithromycin, the hepatitis C protease inhibitor telaprevir, combinations of HIV protease inhibitors, including saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, and fosamprenavir plus ritonavir, niacin, or azole antifungals. Physicians considering combined therapy with atorvastatin calcium and fibric acid derivatives, erythromycin, clarithromycin, a combination of saquinavir plus ritonavir, lopinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, azole antifungals, or lipid-modifying doses of niacin should carefully weigh the potential benefits and risks and should carefully monitor patients for any signs or symptoms of muscle pain, tenderness, or weakness, particularly during the initial months of therapy and during any periods of upward dosage titration of either drug. Lower starting and maintenance doses of atorvastatin should be considered when taken concomitantly with the aforementioned drugs [see **DRUG INTERACTIONS (7)**]. Periodic creatine phosphokinase (CPK) determinations may be considered in such situations, but there is no assurance that such monitoring will prevent the occurrence of severe myopathy.

Prescribing recommendations for interacting agents are summarized in **Table 1** [see also **DOSAGE AND ADMINISTRATION (2.6)**, **DRUG INTERACTIONS (7)**, **CLINICAL PHARMACOLOGY (12.3)**].

Table 1. Drug Interactions Associated with Increased Risk of Myopathy/Rhabdomyolysis

Interacting Agents	Prescribing Recommendations
Cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir)	Avoid atorvastatin
HIV protease inhibitor (lopinavir plus ritonavir)	Use with caution and lowest dose necessary
Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir*, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir)	Do not exceed 20 mg atorvastatin daily
HIV protease inhibitor (nelfinavir)	Do not exceed 40 mg atorvastatin daily

*Use with caution and with the lowest dose necessary (12.3)

Cases of myopathy, including rhabdomyolysis, have been reported with atorvastatin co-administered with colchicine, and caution should be exercised when prescribing atorvastatin with colchicine [see **DRUG INTERACTIONS (7.11)**].

Atorvastatin calcium therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).

5.2 Liver Dysfunction

Statins, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. **Persistent elevations (>3 times the upper limit of normal [ULN] occurring on 2 or more occasions) in serum transaminases occurred in 0.7% of patients who received atorvastatin calcium in clinical trials. The incidence of these abnormalities was 0.2%, 0.2%, 0.6%, and 2.3% for 10, 20, 40, and 80 mg, respectively.**

One patient in clinical trials developed jaundice. Increases in liver function tests (LFT) in other patients were not associated with jaundice or other clinical signs or symptoms. Upon dose reduction, drug interruption, or discontinuation, transaminase levels returned to or near pretreatment levels without sequelae. Eighteen of 30 patients with persistent LFT elevations continued treatment with a reduced dose of atorvastatin calcium.

It is recommended that liver enzyme tests be obtained prior to initiating therapy with atorvastatin calcium and repeated as clinically indicated. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including atorvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with atorvastatin calcium, promptly interrupt therapy. If an alternate etiology is not found, do not restart atorvastatin calcium.

Atorvastatin calcium should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contraindications to the use of atorvastatin calcium [see **CONTRAINDICATIONS (4.1)**].

5.3 Endocrine Function

Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including atorvastatin calcium.

Statins interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. Clinical studies have shown that atorvastatin calcium does not reduce basal plasma cortisol concentration or impair adrenal reserve. The effects of statins on male fertility have not been studied in adequate numbers of patients. The effects, if any, on the pituitary-gonadal axis in premenopausal women are unknown. Caution should be exercised if a statin is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

5.4 CNS Toxicity

Brain hemorrhage was seen in a female dog treated for 1 month at 120 mg/kg/day. Brain hemorrhage and optic nerve vacuolation were seen in another female dog that was sacrificed in moribund condition after 11 weeks of escalating doses up to 280 mg/kg/day. The 120 mg/kg dose resulted in a systemic exposure approximately 16 times the human plasma area-under-the-curve (AUC, 0–24 hours) based on the maximum human dose of 80 mg/day. A single tonic convulsion was seen in each of 2 male dogs (one treated at 10 mg/kg/day and one at 120 mg/kg/day) in a 2-year study. No CNS lesions have been observed in mice after chronic treatment for up to 2 years at doses up to 400 mg/kg/day or in rats at doses up to 100 mg/kg/day. These doses were 6 to 11 times (mouse) and 8 to 16 times (rat) the human AUC (0–24) based on the maximum recommended human dose of 80 mg/day.

CNS vascular lesions, characterized by perivascular hemorrhages, edema, and mononuclear cell infiltration of perivascular spaces, have been observed in dogs treated with other members of this class. A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion at a dose that produced plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose.

5.5 Use in Patients with Recent Stroke or TIA

In a post-hoc analysis of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study where atorvastatin calcium 80 mg vs. placebo was administered in 4,731 subjects without CHD who had a stroke or TIA within the preceding 6 months, a higher incidence of hemorrhagic stroke was seen in the atorvastatin calcium 80 mg group compared to placebo (55, 2.3% atorvastatin vs. 33, 1.4% placebo; HR: 1.68, 95% CI: 1.09, 2.59; p=0.0168). The incidence of fatal hemorrhagic stroke was similar across treatment groups (17 vs. 18 for the atorvastatin and placebo groups, respectively). The incidence of nonfatal hemorrhagic stroke was significantly higher in the atorvastatin group (38, 1.6%) as compared to the placebo group (16, 0.7%). Some baseline characteristics, including hemorrhagic and lacunar stroke on study entry, were associated with a higher incidence of hemorrhagic stroke in the atorvastatin group [see **ADVERSE REACTIONS (6.1)**].

6. ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the label:
Rhabdomyolysis and myopathy [see **WARNINGS AND PRECAUTIONS (5.1)**]
Liver enzyme abnormalities [see **WARNINGS AND PRECAUTIONS (5.2)**]

6.1 Clinical Trial Adverse Experiences

Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the atorvastatin calcium placebo-controlled clinical trial database of 16,066 patients (8755 atorvastatin calcium vs. 7311 placebo; age range 10 to 93 years, 39% women, 91% Caucasians, 3% Blacks, 2% Asians, 4% other) with a median treatment duration of 53 weeks, 9.7% of patients on atorvastatin calcium and 9.5% of the patients on placebo discontinued due to adverse reactions regardless of causality. The five most common adverse reactions in patients treated with atorvastatin calcium that led to treatment discontinuation and occurred at a rate greater than placebo were: myalgia (0.7%), diarrhea (0.5%), nausea (0.4%), alanine aminotransferase increase (0.4%), and hepatic enzyme increase (0.4%).

The most commonly reported adverse reactions (incidence ≥ 2% and greater than placebo) regardless of causality, in patients treated with atorvastatin calcium in placebo controlled trials (n=8755) were: nasopharyngitis (8.3%), arthralgia (6.9%), diarrhea (6.8%), pain in extremity (6%), and urinary tract infection (5.7%).

Table 2 summarizes the frequency of clinical adverse reactions, regardless of causality, reported in ≥ 2% and at a rate greater than placebo in patients treated with atorvastatin calcium (n=8755), from seventeen placebo-controlled trials.

Table 2. Clinical adverse reactions occurring in ≥ 2% in patients treated with any dose of atorvastatin calcium and at an incidence greater than placebo regardless of causality (% of patients).

Adverse Reaction[a]	Any dose N= 8755	10 mg N= 3908	20 mg N= 188	40 mg N= 604	80 mg N= 4055	Placebo N=7311
Nasopharyngitis	8.3	8.0	5.3	7	4.2	8.2
Arthralgia	6.9	6.9	11.7	10.6	4.3	6.5
Diarrhea	6.8	7.3	6.4	14.1	5.2	6.3
Pain in extremity	6	8.5	3.7	9.3	3.1	5.9
Urinary tract infection	5.7	6.9	6.4	8	4.1	5.6
Dyspepsia	4.7	5.9	3.2	6	3.3	4.3
Nausea	4	3.7	3.7	7.1	3.8	3.5
Musculoskeletal pain	3.8	5.2	3.2	5.1	2.3	3.6
Muscle Spasms	3.6	4.6	4.8	5.1	2.4	3
Myalgia	3.5	3.6	5.9	9.4	2.7	3.1
Insomnia	3	2.8	1.1	5.3	2.6	2.9
Pharyngolaryngeal pain	2.3	3.9	1.6	2.8	0.7	2.1

a) Adverse Reaction ≥ 2% in any dose greater than placebo

Other adverse reactions reported in placebo-controlled studies include:

Body as a whole: malaise, pyrexia; *Digestive system:* abdominal discomfort, eructation, flatulence, hepatitis, cholestasis; *Musculoskeletal system:* musculoskeletal pain, muscle fatigue, neck pain, joint swelling; *Metabolic and nutritional system:* transaminases increase, liver function test abnormal, blood alkaline phosphatase increase, creatine phosphokinase increase, hyperglycemia; *Nervous system:* nightmare; *Respiratory system:* epistaxis; *Skin and appendages:* urticaria; *Special senses:* vision blurred, tinnitus; *Urogenital system:* white blood cells urine positive.

Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT)
In ASCOT [see **CLINICAL STUDIES (14.1)**] involving 10,305 participants (age range 40 to 80 years, 19% women; 94.6% Caucasians, 2.6% Africans, 1.5% South Asians, 1.3% mixed/other) treated with atorvastatin calcium 10 mg daily (n=5,168) or placebo (n=5,137), the safety and tolerability profile of the group treated with atorvastatin calcium was comparable to that of the group treated with placebo during a median of 3.3 years of follow-up.

Collaborative Atorvastatin Diabetes Study (CARDS)
In CARDS [see **CLINICAL STUDIES (14.1)**] involving 2,838 subjects (age range 39 to 77 years, 32% women; 94.3% Caucasians, 2.4% South Asians, 2.3% Afro-Caribbean, 1% other) with type 2 diabetes treated with atorvastatin calcium 10 mg daily (n=1,428) or placebo (n=1,410), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 3.9 years. No cases of rhabdomyolysis were reported.

Treating to New Targets Study (TNT)
In TNT [see **CLINICAL STUDIES (14.1)**] involving 10,001 subjects (age range 29 to 78 years, 19% women; 94.1% Caucasians, 2.9% Blacks, 1% Asians, 2% other) with clinically evident CHD treated with atorvastatin calcium 10 mg daily (n=5006) or atorvastatin calcium 80 mg daily (n=4995), there were more serious adverse reactions and discontinuations due to adverse reactions in the high-dose atorvastatin group (92, 1.8%; 446, 8.9%, respectively) as compared to the low-dose group (69, 1.4%; 404, 8.1%, respectively) during a median follow-up of 4.9 years. Persistent transaminase elevations (≥3 × ULN twice within 4 to 10 days) occurred in 62 (1.3%) individuals with atorvastatin 80 mg and in nine (0.2%) individuals with atorvastatin 10 mg. Elevations of CK (≥ 10 × ULN) were low overall, but were higher in the high-dose atorvastatin treatment group (13, 0.3%) compared to the low-dose atorvastatin group (6, 0.1%).

Incremental Decrease in Endpoints through Aggressive Lipid Lowering Study (IDEAL)
In IDEAL [see **CLINICAL STUDIES (14.1)**] involving 8,888 subjects (age range 26 to 80 years, 19% women; 99.3% Caucasians, 0.4% Asians, 0.3% Blacks, 0.04% other) treated with atorvastatin calcium 80 mg/day (n=4439) or simvastatin 20 to 40 mg daily (n=4449), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 4.8 years.

Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL)
In SPARCL involving 4731 subjects (age range 21 to 92 years, 40% women; 93.3% Caucasians, 3% Blacks, 0.6% Asians, 3.1% other) without clinically evident CHD but with a stroke or transient ischemic attack (TIA) within the previous 6 months treated with atorvastatin calcium 80 mg (n=2365) or placebo (n=2366) for a median follow-up of 4.9 years, there was a higher incidence of persistent hepatic transaminase elevations (≥ 3 × ULN twice within 4–10 days) in the atorvastatin group (0.9%) compared to placebo (0.1%). Elevations of CK (>10 × ULN) were rare, but were higher in the atorvastatin group (0.1%) compared to placebo (0%). Diabetes was reported as an adverse reaction in 144 subjects (6.1%) in the atorvastatin group and 89 subjects (3.8%) in the placebo group [see **WARNINGS AND PRECAUTIONS (5.5)**].

In a post-hoc analysis, atorvastatin calcium 80 mg reduced the incidence of ischemic stroke (218/2365, 9.2% vs. 274/2366, 11.6%) and increased the incidence of hemorrhagic stroke (55/2365, 2.3% vs. 33/2366, 1.4%) compared to placebo. The incidence of fatal hemorrhagic stroke was similar between groups (17 atorvastatin calcium vs. 18 placebo). The incidence of non-fatal hemorrhagic strokes was significantly greater in the atorvastatin group (38 non-fatal hemorrhagic strokes) as compared to the placebo group (16 non-fatal hemorrhagic strokes). Subjects who entered the study with a hemorrhagic stroke appeared to be at increased risk for hemorrhagic stroke [7 (16%) atorvastatin calcium vs. 2 (4%) placebo].

There were no significant differences between the treatment groups for all-cause mortality: 216 (9.1%) in the atorvastatin calcium 80 mg/day group vs. 211 (8.9%) in the placebo group. The proportions of subjects who experienced cardiovascular death were numerically smaller in the atorvastatin calcium 80 mg group (3.3%) than in the placebo group (4.1%). The proportions of subjects who experienced non-cardiovascular death were numerically larger in the atorvastatin calcium 80 mg group (5%) than in the placebo group (4%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of atorvastatin calcium. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions associated with atorvastatin calcium therapy reported since market introduction, that are not listed above, regardless of causality assessment, include the following: anaphylaxis, angioneurotic edema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), rhabdomyolysis, fatigue, tendon rupture, fatal and non-fatal hepatic failure, dizziness, depression, peripheral neuropathy, and pancreatitis.

There have been rare postmarketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally nonserious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).

6.3 Pediatric Patients (ages 10 to 17 years)

In a 26-week controlled study in boys and postmenarchal girls (n=140, 31% female; 92% Caucasians, 1.6% Blacks, 1.6% Asians, 4.8% other), the safety and tolerability profile of atorvastatin calcium 10 to 20 mg daily was generally similar to that of placebo [see **CLINICAL STUDIES (14.6)** and **USE IN SPECIAL POPULATIONS, Pediatric Use (8.4)**].

7. DRUG INTERACTIONS

The risk of myopathy during treatment with statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP 3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole) [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **CLINICAL PHARMACOLOGY (12.3)**].

7.1 Strong Inhibitors of CYP 3A4

Atorvastatin calcium is metabolized by cytochrome P450 3A4. Concomitant administration of atorvastatin calcium with strong inhibitors of CYP 3A4 can lead to increases in plasma concentrations of atorvastatin. The extent of interaction and potentiation of effects depend on the variability of effect on CYP 3A4.

Clarithromycin
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 80 mg with clarithromycin (500 mg twice daily) compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking clarithromycin, caution should be used when the atorvastatin calcium dose exceeds 20 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Combination of Protease Inhibitors
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium with several combinations of HIV protease inhibitors, as well as with the hepatitis C protease inhibitor telaprevir, compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking the HIV protease inhibitor tipranavir plus ritonavir, or the hepatitis C protease inhibitor telaprevir, concomitant use of atorvastatin calcium should be avoided. In patients taking the HIV protease inhibitor lopinavir plus ritonavir, caution should be used when prescribing atorvastatin calcium and the lowest dose necessary should be used. In patients taking the HIV protease inhibitors saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, or fosamprenavir plus ritonavir, the dose of atorvastatin calcium should not exceed 20 mg and should be used with caution [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Itraconazole
Atorvastatin AUC was significantly increased with concomitant

AND ADMINISTRATION, Dosage in Patients with Renal Impairment (2.5), **WARNINGS AND PRECAUTIONS**, **Skeletal Muscle (5.1)**].

Hemodialysis: While studies have not been conducted in patients with end-stage renal disease, hemodialysis is not expected to significantly enhance clearance of atorvastatin calcium since the drug is extensively bound to plasma proteins.

Hepatic Impairment: In patients with chronic alcoholic liver disease, plasma concentrations of atorvastatin calcium are markedly increased. C_{max} and AUC are each 4-fold greater in patients with Childs-Pugh A disease. C_{max} and AUC are approximately 16-fold and 11-fold increased, respectively, in patients with Childs-Pugh B disease [see **CONTRAINDICATIONS (4.1)**].

TABLE 3. Effect of Co-administered Drugs on the Pharmacokinetics of Atorvastatin

Co-administered drug and dosing regimen	Atorvastatin		
	Dose (mg)	Change in AUC[b]	Change in C_{max}[c]
[a]Cyclosporine 5.2 mg/kg/day, stable dose	10 mg QD for 28 days	↑ 8.7 fold	↑10.7 fold
[d]Tipranavir 500 mg BID/ ritonavir 200 mg BID, 7 days	10 mg, SD	↑ 9.4 fold	↑ 8.6 fold
[e]Telaprevir 750 mg q8h, 10 days	20 mg, SD	↑ 7.88 fold	↑ 10.6 fold
[e,f]Saquinavir 400 mg BID/ ritonavir 400 mg BID, 15 days	40 mg QD for 4 days	↑ 3.9 fold	↑ 4.3 fold
[a]Clarithromycin 500 mg BID, 9 days	80 mg QD for 8 days	↑ 4.4 fold	↑ 5.4 fold
[a]Darunavir 300 mg BID/ ritonavir 100 mg BID, 9 days	10 mg QD for 4 days	↑ 3.4 fold	↑ 2.25 fold
[a]Itraconazole 200 mg QD, 4 days	40 mg SD	↑ 3.3 fold	↑ 20%
[a]Fosamprenavir 700 mg BID/ ritonavir 100 mg BID, 14 days	10 mg QD for 4 days	↑ 2.53 fold	↑ 2.84 fold
[a]Fosamprenavir 1400 mg BID, 14 days	10 mg QD for 4 days	↑ 2.3 fold	↑ 4.04 fold
[a]Nelfinavir 1250 mg BID, 14 days	10 mg QD for 28 days	↑ 74%	↑ 2.2 fold
[a]Grapefruit Juice, 240 mL QD [g]	40 mg, SD	↑ 37%	↑ 16%
Diltiazem 240 mg QD, 28 days	40 mg, SD	↑ 51%	No change
Erythromycin 500 mg QID, 7 days	10 mg, SD	↑ 33%	↑ 38%
Amlodipine 10 mg, single dose	80 mg, SD	↑ 15%	↓ 12 %
Cimetidine 300 mg QID, 4 weeks	10 mg QD for 2 weeks	↓ Less than 1%	↓ 11%
Colestipol 10 mg BID, 28 weeks	40 mg QD for 28 weeks	Not determined	↓ 26%[h]
Maalox TC® 30 mL QD, 17 days	10 mg QD for 15 days	↓ 33%	↓ 34%
Efavirenz 600 mg QD, 14 days	10 mg for 3 days	↓ 41%	↓ 1%
[a]Rifampin 600 mg QD, 7 days (co-administered) [e]	40 mg SD	↑ 30%	↑ 2.7 fold
[a]Rifampin 600 mg QD, 5 days (doses separated) [e]	40 mg SD	↓ 80%	↓ 40%
[i]Gemfibrozil 600 mg BID, 7 days	40 mg SD	↑ 35%	↓ Less than 1%
[j]Fenofibrate 160 mg QD, 7 days	40 mg SD	↑ 3%	↑ 2%

a) Data given as x-fold change represent a simple ratio between co-administration and atorvastatin alone (i.e., 1-fold = no change). Data given as % change represent % difference relative to atorvastatin alone (i.e., 0% = no change).
b) See Sections 5.1 and 7 for clinical significance.
c) Greater increases in AUC (up to 2.5 fold) and/ or Cmax (up to 71%) have been reported with excessive grapefruit consumption (≥ 750 mL to 1.2 liters per day).
d) Single sample taken 8 to 16 h post dose.
e) Due to the dual interaction mechanism of rifampin, simultaneous co-administration of atorvastatin with rifampin is recommended, as delayed administration of atorvastatin after administration of rifampin has been associated with a significant reduction in atorvastatin plasma concentrations.
f) The dose of saquinavir plus ritonavir in this study is not the clinically used dose. The increase in atorvastatin exposure when used clinically is likely to be higher than what was observed in this study. Therefore, caution should be applied and the lowest dose necessary should be used.

TABLE 4. Effect of Atorvastatin on the Pharmacokinetics of Co-administered Drugs

Atorvastatin	Co-administered drug and dosing regimen		
	Drug/Dose (mg)	Change in AUC	Change in C_{max}
80 mg QD for 15 days	Antipyrine, 600 mg SD	↑ 3%	↓ 11%
80 mg QD for 14 days	[a]Digoxin 0.25 mg QD, 20 days	↑ 15%	↑ 20 %
40 mg QD for 22 days	Oral contraceptive QD, 2 months - norethindrone 1 mg - ethinyl estradiol 35 mcg	↑ 28% ↑ 19%	↑ 23% ↑ 30%
10 mg, SD	Tipranavir 500 mg BID/ritonavir 200 mg BID, 7 days	No change	No change
10 mg QD for 4 days	Fosamprenavir 1400 mg BID, 14 days	↓ 27%	↓ 18%
10 mg QD for 4 days	Fosamprenavir 700 mg BID/ ritonavir 100 mg BID, 14 days	No change	No change

a) See **Section 7** for clinical significance.

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
In a 2-year carcinogenicity study in rats at dose levels of 10, 30, and 100 mg/kg/day, 2 rare tumors were found in muscle in high-dose females: in one, there was a rhabdomyosarcoma and, in another, there was a fibrosarcoma. This dose represents a plasma AUC (0-24) value of approximately 16 times the mean human plasma drug exposure after an 80 mg oral dose.

A 2-year carcinogenicity study in mice given 100, 200, or 400 mg/kg/day resulted in a significant increase in liver adenomas in high-dose males and liver carcinomas in high-dose females. These findings occurred at plasma AUC (0-24) values of approximately 6 times the mean human plasma drug exposure after an 80 mg oral dose.

In vitro, atorvastatin was not mutagenic or clastogenic in the following tests with and without metabolic activation: the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the HGPRT forward mutation assay in Chinese hamster lung cells, and the chromosomal aberration assay in Chinese hamster lung cells. Atorvastatin was negative in the *in vivo* mouse micronucleus test.

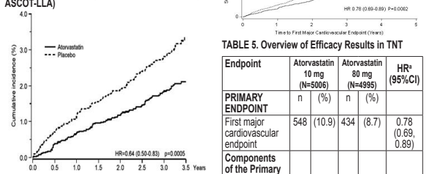
Studies in rats performed at doses up to 175 mg/kg (15 times the human exposure) produced no changes in fertility. There was aplasia and aspermia in the epididymis of 2 of 10 rats treated with 100 mg/kg/day of atorvastatin for 3 months (16 times the human AUC at the 80 mg dose); testis weights were significantly lower at 30 and 100 mg/kg and epididymal weight was lower at 100 mg/kg. Male rats given 100 mg/kg/day for 11 weeks prior to mating had decreased sperm motility, spermatid head concentration, and increased abnormal sperm. Atorvastatin caused no adverse effects on semen parameters, or reproductive organ histopathology in dogs given doses of 10, 40, or 120 mg/kg for two years.

14. CLINICAL STUDIES
14.1 Prevention of Cardiovascular Disease
In the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), the effect of atorvastatin calcium on fatal and non-fatal coronary heart disease was assessed in 10,305 hypertensive patients 40 to 80 years of age (mean of 63 years), without a previous myocardial infarction and with TC levels ≤251 mg/dL (6.5 mmol/L). Additionally, all patients had at least 3 of the following cardiovascular risk factors: male gender (81.1%), age >55 years (84.5%), smoking (33.2%), diabetes (24.3%), history of CHD in a first-degree relative (26%), TC:HDL >6 (14.3%), peripheral vascular disease (5.1%), left ventricular hypertrophy (14.4%), prior cerebrovascular event (9.8%), specific ECG abnormality (14.3%), proteinuria/albuminuria (62.4%). In this double-blind, placebo-controlled study, patients were treated with anti-hypertensive therapy (Goal BP <140/90 mm Hg for non-diabetic patients; <130/80 mm Hg for diabetic patients) and allocated to either atorvastatin calcium 10 mg daily (n=5168) or placebo (n=5137), using a covariate adaptive method which took into account the distribution of nine baseline characteristics of patients already enrolled and minimized the imbalance of those characteristics across the groups. Patients were followed for a median duration of 3.3 years.

The effect of 10 mg/day of atorvastatin calcium on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of coronary events [either fatal coronary heart disease (46 events in the placebo group vs. 40 events in the atorvastatin calcium group) or non-fatal MI (108 events in the placebo group vs. 60 events in the atorvastatin calcium group)] with a relative risk reduction of 36% [based on incidences of 1.9% for atorvastatin calcium vs. 3% for placebo), p=0.0005 (see **Figure 1**)]. The risk reduction was consistent regardless of age, smoking status, obesity, or presence of renal dysfunction. The effect of atorvastatin calcium was seen regardless of baseline LDL levels. Due to the small number of events, results for women were inconclusive.

Figure 1: Effect of Atorvastatin Calcium 10 mg/day on Cumulative Incidence of Non-Fatal Myocardial Infarction or Coronary Heart Disease Death (in ASCOT-LLA)



Atorvastatin calcium also significantly decreased the relative risk for revascularization procedures by 42%. Although the reduction of fatal and non-fatal strokes did not reach a pre-defined significance level (p=0.01), a favorable trend was observed with a 26% relative risk reduction (incidences of 1.7% for atorvastatin calcium and 2.3% for placebo). There was no significant difference between the treatment groups for death due to cardiovascular causes (p=0.51) or noncardiovascular causes (p=0.17).

In the Collaborative Atorvastatin Diabetes Study (CARDS), the effect of atorvastatin calcium on cardiovascular disease (CVD) endpoints was assessed in 2838 subjects (94% white, 68% male), ages 40 to 75 with type 2 diabetes based on WHO criteria, without prior history of cardiovascular disease and with LDL ≤ 160 mg/dL and TG ≤ 600 mg/dL. In addition to diabetes, subjects had 1 or more of the following risk factors: current smoking (23%), hypertension (80%), retinopathy (30%), or microalbuminuria (9%) or macroalbuminuria (3%). No subjects on hemodialysis were enrolled in the study. In this multicenter, placebo-controlled, double-blind clinical trial, subjects were randomly allocated to either atorvastatin calcium 10 mg daily (1429) or placebo (1411) in a 1:1 ratio and were followed for a median duration of 3.9 years. The primary endpoint was the occurrence of any of the major cardiovascular events: myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke. The primary analysis was the time to first occurrence of the primary endpoint.

Baseline characteristics of subjects were: mean age of 62 years, mean HbA, 7.7%; median LDL-C 120 mg/dL; median TC 207 mg/dL; median TG 151 mg/dL; median HDL-C 52 mg/dL.

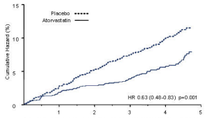
The effect of atorvastatin calcium 10 mg/day on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of major cardiovascular events (primary endpoint events) (83 events in the atorvastatin calcium group vs. 127 events in the placebo group) with a relative risk reduction of 37%, HR 0.63, 95% CI (0.48, 0.83) (p=0.001) (see **Figure 2**). An effect of atorvastatin calcium was seen regardless of age, sex, or baseline lipid levels.

Atorvastatin calcium significantly reduced the risk of stroke by 48% (21 events in the atorvastatin calcium group vs. 39 events in the placebo group), HR 0.52, 95% CI (0.31, 0.89) (p=0.016) and reduced the risk of MI by 42% (38 events in the atorvastatin calcium group vs. 64 events in the placebo group), HR 0.58, 95.1% CI (0.39, 0.86) (p=0.007). There was no significant difference between the treatment groups for angina, revascularization procedures, and acute CHD death.

There were 61 deaths in the atorvastatin calcium group vs. 82 deaths in the placebo group (HR 0.73, p=0.059).

Figure 2: Effect of Atorvastatin Calcium 10 mg/day on Time to Occurrence of Major Cardiovascular Event (myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke) in CARDS



In the Treating to New Targets Study (TNT), the effect of atorvastatin calcium 80 mg/day vs. atorvastatin calcium 10 mg/day on the reduction in cardiovascular events was assessed in 10,001 subjects (94% white, 81% male, 38% ≥65 years) with clinically evident coronary heart disease who had achieved a target LDL-C level <130 mg/dL after completing an 8-week, open-label, run-in period with atorvastatin calcium 10 mg/day. Subjects were randomly assigned to either 10 mg/day or 80 mg/day of atorvastatin calcium and followed for a median duration of 4.9 years. The primary endpoint was the time-to-first occurrence of any of the following major cardiovascular events (MCVE): death due to CHD, non-fatal myocardial infarction, resuscitated cardiac arrest, and fatal and non-fatal stroke. The mean LDL-C, TC, TG, non-HDL, and HDL cholesterol levels at 12 weeks were 73, 145, 128, 98, and 47 mg/dL during treatment with 80 mg of atorvastatin calcium and 99, 177, 152, 129, and 48 mg/dL during treatment with 10 mg of atorvastatin calcium.

Treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of MCVE (434 events in the 80 mg/day group vs. 548 events in the 10 mg/day group) with a relative risk reduction of 22%, HR 0.78, 95% CI (0.69, 0.89), p=0.0002 (see **Figure 3** and **Table 5**). The overall risk reduction was consistent regardless of age (<65, ≥65) or gender.

Figure 3: Effect of Atorvastatin Calcium 80 mg/day vs. 10 mg/day on Time to Occurrence of Major Cardiovascular Events (TNT)

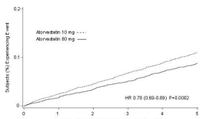


TABLE 5. Overview of Efficacy Results in TNT

Endpoint	Atorvastatin 10 mg (N=5006)		Atorvastatin 80 mg (N=4995)		HR[a] (95%CI)
	n	(%)	n	(%)	
PRIMARY ENDPOINT					
First major cardiovascular endpoint	548	(10.9)	434	(8.7)	0.78 (0.69, 0.89)
Components of the Primary Endpoint					
CHD death	127	(2.5)	101	(2)	0.80 (0.61, 1.03)
Non-fatal, non-procedure related MI	308	(6.2)	243	(4.9)	0.78 (0.66, 0.93)
Resuscitated cardiac arrest	26	(0.5)	25	(0.5)	0.96 (0.56, 1.67)
Stroke (fatal and non-fatal)	155	(3.1)	117	(2.3)	0.75 (0.59, 0.96)
SECONDARY ENDPOINTS					
First CHF with hospitalization	164	(3.3)	122	(2.4)	0.74 (0.59, 0.94)
First PVD endpoint	282	(5.6)	275	(5.5)	0.97 (0.83, 1.15)
First CABG or other coronary revascularization procedure[b]	904	(18.1)	667	(13.4)	0.72 (0.65, 0.80)
First documented angina endpoint[b]	615	(12.3)	545	(10.9)	0.88 (0.79, 0.99)
All-cause mortality	282	(5.6)	284	(5.7)	1.01 (0.85, 1.19)
Components of All-Cause Mortality					
Cardiovascular death	155	(3.1)	126	(2.5)	0.81 (0.64, 1.03)
Noncardiovascular death	127	(2.5)	158	(3.2)	1.25 (0.99, 1.57)
Cancer death	75	(1.5)	85	(1.7)	1.13 (0.83, 1.55)
Other non-CV death	43	(0.9)	58	(1.2)	1.35 (0.91, 2)
Suicide, homicide, and other traumatic non CV death	9	(0.2)	15	(0.3)	1.67 (0.73, 3.82)

a) Atorvastatin 80 mg: atorvastatin 10 mg
b) Component of other secondary endpoints
Secondary endpoints not included in primary endpoint

HR=hazard ratio; CHD=coronary heart disease; CI=confidence interval; MI=myocardial infarction; CHF=congestive heart failure; CV=cardiovascular; PVD=peripheral vascular disease; CABG=coronary artery bypass graft
Confidence intervals for the Secondary Endpoints were not adjusted for multiple comparisons

Of the events that comprised the primary efficacy endpoint, treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of non-fatal, non-procedure related MI and fatal and non-fatal stroke, but not CHD death or resuscitated cardiac arrest (**Table 5**). Of the predefined secondary endpoints, treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of coronary revascularization, angina, and hospitalization for heart failure, but not peripheral vascular disease. The reduction in the rate of CHF with hospitalization was only observed in the 8% of patients with a prior history of CHF.

There was no significant difference between the treatment groups for all-cause mortality (**Table 5**). The proportions of subjects who experienced cardiovascular death, including the components of CHD death and fatal stroke, were numerically smaller in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group. The proportions of subjects who experienced noncardiovascular death were numerically larger in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group.

In the Incremental Decrease in Endpoints Through Aggressive Lipid Lowering Study (IDEAL), treatment with atorvastatin calcium 80 mg/day was compared to treatment with simvastatin 20 to 40 mg/day in 8,888 subjects up to 80 years of age with a history of CHD to assess whether reduction in CV risk could be achieved. Patients were mainly male (81%), white (99%) with an average age of 61.7 years, and an average LDL-C of 121.5 mg/dL at randomization; 76% were on statin therapy. In this prospective, randomized, open-label, blinded endpoint (PROBE) trial with no run-in period, subjects were followed for a median duration of 4.8 years. The mean LDL-C, TC, TG, HDL, and non-HDL cholesterol levels at Week 12 were 78, 145, 115, 45, and 100 mg/dL during treatment with 80 mg of atorvastatin calcium and 105, 179, 142, 47, and 132 mg/dL during treatment with 20 to 40 mg of simvastatin.

There was no significant difference between the treatment groups for the primary endpoint, the rate of first major coronary event (fatal CHD, non-fatal MI, and resuscitated cardiac arrest): 411 (9.3%) in the atorvastatin calcium 80 mg/day group vs. 463 (10.4%) in the simvastatin 20 to 40 mg/day group, HR 0.89, 95% CI (0.78, 1.01), p=0.07.

There were no significant differences between the treatment groups for all-cause mortality: 366 (8.2%) in the atorvastatin calcium 80 mg/day group vs. 374 (8.4%) in the simvastatin 20 to 40 mg/day group. The proportions of subjects who experienced CV or non-CV death were similar for the atorvastatin calcium 80 mg group and the simvastatin 20 to 40 mg group.

14.2 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia *(Fredrickson* Types IIa and IIb)
Atorvastatin calcium reduces total-C, LDL-C, VLDL-C, apo B, and TG, and increases HDL-C in patients with hyperlipidemia and mixed dyslipidemia. Therapeutic response is seen within 2 weeks, and maximum response is usually achieved within 4 weeks and maintained during chronic therapy.

Atorvastatin calcium is effective in a wide variety of patient populations with hyperlipidemia, with and without hypertriglyceridemia, in men and women, and in the elderly.

In two multicenter, placebo-controlled, dose-response studies in patients with hyperlipidemia, atorvastatin calcium given as a single dose over 6 weeks, significantly reduced total-C, LDL-C, apo B, and TG. (Pooled results are provided in **Table 6**.)

TABLE 6. Dose Response in Patients With Primary Hyperlipidemia (Adjusted Mean % Change From Baseline)[a]

Dose	N	TC	LDL-C	Apo B	TG	HDL-C	Non-HDL-C/ HDL-C
Placebo	21	4	4	3	10	-3	7
10	22	-29	-39	-32	-19	6	-34
20	20	-33	-43	-35	-26	9	-41
40	21	-37	-50	-42	-29	6	-45
80	23	-45	-60	-50	-37	5	-53

a) Results are pooled from 2 dose-response studies.

In patients with *Fredrickson* Types IIa and IIb hyperlipoproteinemia pooled from 24 controlled trials, the median (25th and 75th percentile) percent changes from baseline in HDL-C for atorvastatin calcium 10, 20, 40, and 80 mg were 6.4 (-1.4, 14), 8.7 (0, 17), 7.8 (0, 16), and 5.1 (-2.7, 15), respectively. Additionally, analysis of the pooled data demonstrated consistent and significant decreases in total-C, LDL-C, TG, total-C/HDL-C, and LDL-C/HDL-C.

In three multicenter, double-blind studies in patients with hyperlipidemia, atorvastatin calcium was compared to other statins. After randomization, patients were treated for 16 weeks with either atorvastatin calcium 10 mg per day or a fixed dose of the comparative agent (**Table 7**).

TABLE 7. Mean Percentage Change From Baseline at Endpoint (Double-Blind, Randomized, Active-Controlled Trials)

Treatment (Daily Dose)	N	Total -C	LDL -C	Apo B	TG	HDL -C	Non-HDL-C/ HDL-C
Study 1							
Atorvastatin calcium 10 mg	707	-27*	-36*	-28*	-17*	7	-37*
Lovastatin 20 mg	191	-19	-27	-20	-6	7	-28
95% CI for Diff[a]		-9.2, -6.5	-10.7, -7.1	-10, -6.5	-15.2, -7.1	-1.7, 2	-11.1, -7.1
Study 2							
Atorvastatin calcium 10 mg	222	-25*	-35*	-27*	-17*	6	-36*
Pravastatin 20 mg	77	-17	-23	-17	-9	8	-28
95% CI for Diff[a]		-10.8, -6.1	-14.5, -8.2	-13.4, -7.4	-14.1, -0.7	-4.9, 1.6	-11.5, -4.1
Study 3							
Atorvastatin calcium 10 mg	132	-29*	-37*	-34*	-23*	7	-39*
Simvastatin 10 mg	45	-24	-30	-30	-15	7	-33
95% CI for Diff[a]		-8.7, -2.7	-10.1, -2.6	-8, -1.1	-15.1, -0.7	-4.3, 3.9	-9.6, -1.9

a) A negative value for the 95% CI for the difference between treatments favors atorvastatin calcium for all except HDL-C, for which a positive value favors atorvastatin calcium. If the range does not include 0, this indicates a statistically significant difference.
b) Significantly different from lovastatin, ANCOVA, p ≤0.05
c) Significantly different from pravastatin, ANCOVA, p ≤0.05
d) Significantly different from simvastatin, ANCOVA, p ≤0.05

The impact on clinical outcomes of the differences in lipid-altering effects between treatments shown in **Table 7** is not known. **Table 7** does not contain data comparing the effects of atorvastatin calcium 10 mg and higher doses of lovastatin, pravastatin, and simvastatin. The drugs compared in the studies summarized in the table are not necessarily interchangeable.

14.3 Hypertriglyceridemia *(Fredrickson* Type IV)
The response to atorvastatin calcium in 64 patients with isolated hypertriglyceridemia treated across several clinical trials is shown in the table below (**Table 8**). For the atorvastatin calcium-treated patients, median (min, max) baseline TG level was 565 (267 to 1502).

TABLE 8. Combined Patients With Isolated Elevated TG: Median (min, max) Percentage Change From Baseline

	Placebo (N=12)	Atorvastatin Calcium 10 mg (N=37)	Atorvastatin Calcium 20 mg (N=19)	Atorvastatin Calcium 80 mg (N=14)
Triglycerides	-12.4 (-36.6, 82.7)	-41 (-76.2, 49.4)	-38.7 (-62.7, 29.5)	-51.8 (-82.8, 41.3)
Total-C	-2.3 (-15.5, 24.4)	-28.2 (-44.9, -6.8)	-34.9 (-49.6, -15.2)	-44.4 (-63.5, -3.8)
LDL-C	3.6 (-31.3, 31.6)	-26.5 (-57.7, 9.8)	-30.4 (-53.9, 0.3)	-40.5 (-60.6, -13.8)
HDL-C	3.8 (-18.6, 13.4)	13.8 (-9.7, 61.5)	11 (-3.2, 25.2)	7.5 (-10.8, 37.2)
VLDL-C	-1 (-31.9, 53.2)	-48.8 (-85.8, 57.3)	-44.6 (-62.2, -10.8)	-62 (-88.2, 37.6)
non-HDL-C	-2.8 (-17.6, 30)	-33 (-52.1, -13.3)	-42.7 (-53.7, -17.4)	-51.5 (-72.9, -4.3)

14.4 Dysbetalipoproteinemia *(Fredrickson* Type III)
The results of an open-label crossover study of 16 patients (genotypes: 14 apo E2/E2 and 2 apo E3/E2) with dysbetalipoproteinemia *(Fredrickson* Type III) are shown in the table below (**Table 9**).

TABLE 9. Open-Label Crossover Study of 16 Patients With Dysbetalipoproteinemia (*Fredrickson* Type III)

	Median (min, max) at Baseline (mg/dL)	Median % Change (min, max)	
		Atorvastatin Calcium 10 mg	Atorvastatin Calcium 80 mg
Total-C	442 (225, 1320)	-37 (-85, 17)	-58 (-90, -31)
Triglycerides	678 (273, 5990)	-39 (-92, -8)	-53 (-95, -30)
IDL-C VLDL-C	215 (111, 613)	-32 (-76, 9)	-63 (-90, -8)
non-HDL-C	411 (218, 1272)	-43 (-87, -19)	-64 (-92, -36)

14.5 Homozygous Familial Hypercholesterolemia
In a study without a concurrent control group, 29 patients ages 6 to 37 years with homozygous FH received maximum daily doses of 20 to 80 mg of atorvastatin calcium. The mean LDL-C reduction in this study was 18%. Twenty-five patients with a reduction in LDL-C had a mean response of 20% (range of 7% to 53%, median of 24%); the remaining 4 patients had 7% to 24% increases in LDL-C. Five of the 29 patients had absent LDL-receptor function. Of these, 2 patients also had a portacaval shunt and had no significant reduction in LDL-C. The remaining 3 receptor-negative patients had a mean LDL-C reduction of 22%.

14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
In a double-blind, placebo-controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10 to 17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolemia (FH) or severe hypercholesterolemia, were randomized to atorvastatin calcium (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin calcium for 26 weeks. Inclusion in the study required 1) a baseline LDL-C level ≥ 190 mg/dL or 2) a baseline LDL-C level ≥ 160 mg/dL and positive family history of FH or documented premature cardiovascular disease in a first or second-degree relative. The mean baseline LDL-C value was 218.6 mg/dL (range: 138.5 to 385 mg/dL) in the atorvastatin calcium group compared to 230 mg/dL (range: 160 to 324.5 mg/dL) in the placebo group. The dosage of atorvastatin calcium (once daily) was 10 mg for the first 4 weeks and uptitrated to 20 mg if the LDL-C level was > 130 mg/dL. The number of atorvastatin calcium-treated patients who required uptitration to 20 mg after Week 4 during the double-blind phase was 80 (57.1%).

Atorvastatin calcium significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26-week double-blind phase (see **Table 10**).

TABLE 10. Lipid-altering Effects of Atorvastatin Calcium in Adolescent Boys and Girls with Heterozygous Familial Hypercholesterolemia or Severe Hypercholesterolemia (Mean Percentage Change From Baseline at Endpoint in Intention-to-Treat Population)

DOSAGE	N	Total -C	LDL -C	HDL -C	TG	Apolipo-protein B
Placebo	47	-1.5	-0.4	-1.9	1	0.7
Atorvastatin calcium	140	-31.4	-39.6	2.8	-12	-34

The mean achieved LDL-C value was 130.7 mg/dL (range: 70 to 242 mg/dL) in the atorvastatin calcium group compared to 228.5 mg/dL (range: 152 to 385 mg/dL) in the placebo group during the 26-week double-blind phase.

The safety and efficacy of doses above 20 mg have not been studied in controlled trials in children. The long-term efficacy of atorvastatin calcium therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

15. REFERENCES
[1] National Cholesterol Education Program (NCEP): Highlights of the Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents, *Pediatrics*. 89(3):495–501. 1992.

16. HOW SUPPLIED/STORAGE AND HANDLING
Atorvastatin calcium tablets are supplied as follows:

10 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 10" on one side. Bottles contain desiccant.
NDC 0781-5381-31, bottle of 30 tablets
NDC 0781-5381-92, bottle of 90 tablets
NDC 0781-5381-01, bottle of 100 tablets
NDC 0781-5381-10, bottle of 1000 tablets
NDC 0781-5381-34, bottle of 3000 tablets

20 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 20" on one side. Bottles contain desiccant.
NDC 0781-5382-31, bottle of 30 tablets
NDC 0781-5382-92, bottle of 90 tablets
NDC 0781-5382-01, bottle of 100 tablets
NDC 0781-5382-10, bottle of 1000 tablets
NDC 0781-5382-34, bottle of 3000 tablets

40 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 40" on one side. Bottles contain desiccant.
NDC 0781-5384-31, bottle of 30 tablets
NDC 0781-5384-92, bottle of 90 tablets
NDC 0781-5384-01, bottle of 100 tablets
NDC 0781-5384-10, bottle of 1000 tablets
NDC 0781-5384-22, bottle of 2000 tablets

80 mg, light yellow, dappled, glossy, oval biconvex film-coated tablets, debossed with "HLA 80" on one side. Bottles contain desiccant.
NDC 0781-5388-31, bottle of 30 tablets
NDC 0781-5388-92, bottle of 90 tablets
NDC 0781-5388-01, bottle of 100 tablets
NDC 0781-5388-10, bottle of 1000 tablets

Storage
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

17. PATIENT COUNSELING INFORMATION
Patients taking atorvastatin calcium tablets should be advised that cholesterol is a chronic condition and they should adhere to their medication along with their National Cholesterol Education Program (NCEP)-recommended diet, a regular exercise program as appropriate, and periodic testing of a fasting lipid panel to determine goal attainment.

Patients should be advised about substances they should not take concomitantly with atorvastatin [see **WARNINGS AND PRECAUTIONS (5.1)**]**. Patients should also be advised to inform other healthcare professionals prescribing a new medication that they are taking atorvastatin calcium tablets.**

17.1 Muscle Pain
All patients starting therapy with atorvastatin calcium tablets should be advised of the risk of myopathy and told to report promptly any unexplained muscle pain, tenderness, or weakness. The risk of this occurring is increased when taking certain types of medication or consuming larger quantities (>1 liter) of grapefruit juice. They should discuss all medication, both prescription and over the counter, with their healthcare professional.

17.2 Liver Enzymes
It is recommended that liver enzyme tests be performed before the initiation of atorvastatin calcium tablets and if signs or symptoms of liver injury occur. All patients treated with atorvastatin calcium tablets should be advised to report promptly any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

17.3 Pregnancy
Women of childbearing age should be advised to use an effective method of birth control to prevent pregnancy while using atorvastatin calcium tablets. Discuss future pregnancy plans with your patients, and discuss when to stop atorvastatin calcium tablets if they are trying to conceive. Patients should be advised that if they become pregnant, they should stop taking atorvastatin calcium tablets and call their healthcare professional.

17.4 Breastfeeding
Women who are breastfeeding should be advised to not use atorvastatin calcium tablets. Patients who have a lipid disorder and are breastfeeding, should be advised to discuss the options with their healthcare professional.

PATIENT INFORMATION
Atorvastatin Calcium Tablets

Read the Patient Information that comes with atorvastatin calcium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about atorvastatin calcium tablets, ask your doctor or pharmacist.

What are Atorvastatin Calcium Tablets?
Atorvastatin calcium tablets are a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. Atorvastatin calcium tablets are for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

Atorvastatin calcium tablets can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:
- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

Atorvastatin calcium tablets can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:
- eye problems, kidney problems, smoking, or high blood pressure.

Atorvastatin calcium tablets start to work in about 2 weeks.

What is Cholesterol?
Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

Who Should Not Take Atorvastatin Calcium Tablets?
Do not take atorvastatin calcium tablets if you:
- are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you get pregnant, stop taking atorvastatin calcium tablets and call your doctor right away.
- are breast feeding. Atorvastatin calcium tablets can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to atorvastatin calcium tablets or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Atorvastatin calcium tablets have not been studied in children under 10 years of age.

Before You Start Atorvastatin Calcium Tablets
Tell your doctor if you:
- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with atorvastatin calcium tablets. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:
- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take.
Keep a list of them with you to show your doctor and pharmacist.

How Should I Take Atorvastatin Calcium Tablets?
- Take atorvastatin calcium tablets exactly as prescribed by your doctor. Do not change your dose or stop atorvastatin calcium tabl


(b) (4)

PATIENT INFORMATION

Atorvastatin Calcium Tablets

(150 Units)



46082127

Reference ID: 3119521

PATIENT INFORMATION
Atorvastatin Calcium Tablets

Read the Patient Information that comes with atorvastatin calcium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about atorvastatin calcium tablets, ask your doctor or pharmacist.

What are Atorvastatin Calcium Tablets?
Atorvastatin calcium tablets are a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. Atorvastatin calcium tablets are for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

Atorvastatin calcium tablets can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:
- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

Atorvastatin calcium tablets can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:
- eye problems, kidney problems, smoking, or high blood pressure.

Atorvastatin calcium tablets start to work in about 2 weeks.

What is Cholesterol?
Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

Who Should Not Take Atorvastatin Calcium Tablets?
Do not take atorvastatin calcium tablets if you:
- are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you get pregnant, stop taking atorvastatin calcium tablets and call your doctor right away.
- are breast feeding**.** Atorvastatin calcium tablets can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to atorvastatin calcium tablets or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Atorvastatin calcium tablets have not been studied in children under 10 years of age.

Before You Start Atorvastatin Calcium Tablets
Tell your doctor if you:
- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with atorvastatin calcium tablets. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:
- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take.

Keep a list of them with you to show your doctor and pharmacist.

How Should I Take Atorvastatin Calcium Tablets?
- Take atorvastatin calcium tablets exactly as prescribed by your doctor. Do not change your dose or stop atorvastatin calcium tablets without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with atorvastatin calcium tablets. Your dose of atorvastatin calcium tablets may be changed based on these blood test results.
- Take atorvastatin calcium tablets each day at any time of day at about the same time each day. Atorvastatin calcium tablets can be taken with or without food. Don't break atorvastatin calcium tablets before taking.
- Your doctor should start you on a low-fat diet before giving you atorvastatin calcium tablets. Stay on this low-fat diet when you take atorvastatin calcium tablets.
- If you miss a dose of atorvastatin calcium tablets, take it as soon as you remember. Do not take atorvastatin calcium tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of atorvastatin calcium tablets at the same time.



- If you take too much atorvastatin calcium tablets or overdose, call your doctor or Poison Control Center right away. Or go to the nearest emergency room.

What Should I Avoid While Taking Atorvastatin Calcium Tablets?
- Talk to your doctor before you start any new medicines. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects.
- Do not get pregnant. If you get pregnant, stop taking atorvastatin calcium tablets right away and call your doctor.

What are the Possible Side Effects of Atorvastatin Calcium Tablets?

Atorvastatin calcium tablets can cause serious side effects. These side effects have happened only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or atorvastatin calcium tablets are stopped. These serious side effects include:

- **Muscle problems.** Atorvastatin calcium tablets can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with atorvastatin calcium tablets.
- **Liver problems.** Your doctor should do blood tests to check your liver before you start taking atorvastatin calcium tablets, and if you have symptoms of liver problems while you take atorvastatin calcium tablets. Call your doctor right away if you have the following symptoms of liver problems:
  - feel tired or weak
  - loss of appetite
  - upper belly pain
  - dark amber colored urine
  - yellowing of your skin or the whites of your eyes

Call your doctor right away if you have:
- muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual.
- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- nausea and vomiting.
- passing brown or dark-colored urine.
- you feel more tired than usual
- your skin and whites of your eyes get yellow.
- stomach pain.
- allergic skin reactions.

In clinical studies, patients reported the following common side effects while taking atorvastatin calcium tablets: diarrhea, upset stomach, muscle and joint pain, and alterations in some laboratory blood tests.

The following additional side effects have been reported with atorvastatin calcium tablets:
tiredness, tendon problems, memory loss, and confusion.

Talk to your doctor or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of atorvastatin calcium tablets. Ask your doctor or pharmacist for a complete list.

How do I store Atorvastatin Calcium Tablets?

- Store atorvastatin calcium tablets at room temperature 68° to 77°F (20° to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep atorvastatin calcium tablets and all medicines out of the reach of children.** Be sure that if you throw medicine away, it is out of the reach of children.

General Information About Atorvastatin Calcium Tablets
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use atorvastatin calcium tablets for a condition for which it was not prescribed. Do not give atorvastatin calcium tablets to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about atorvastatin calcium tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about atorvastatin calcium tablets that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

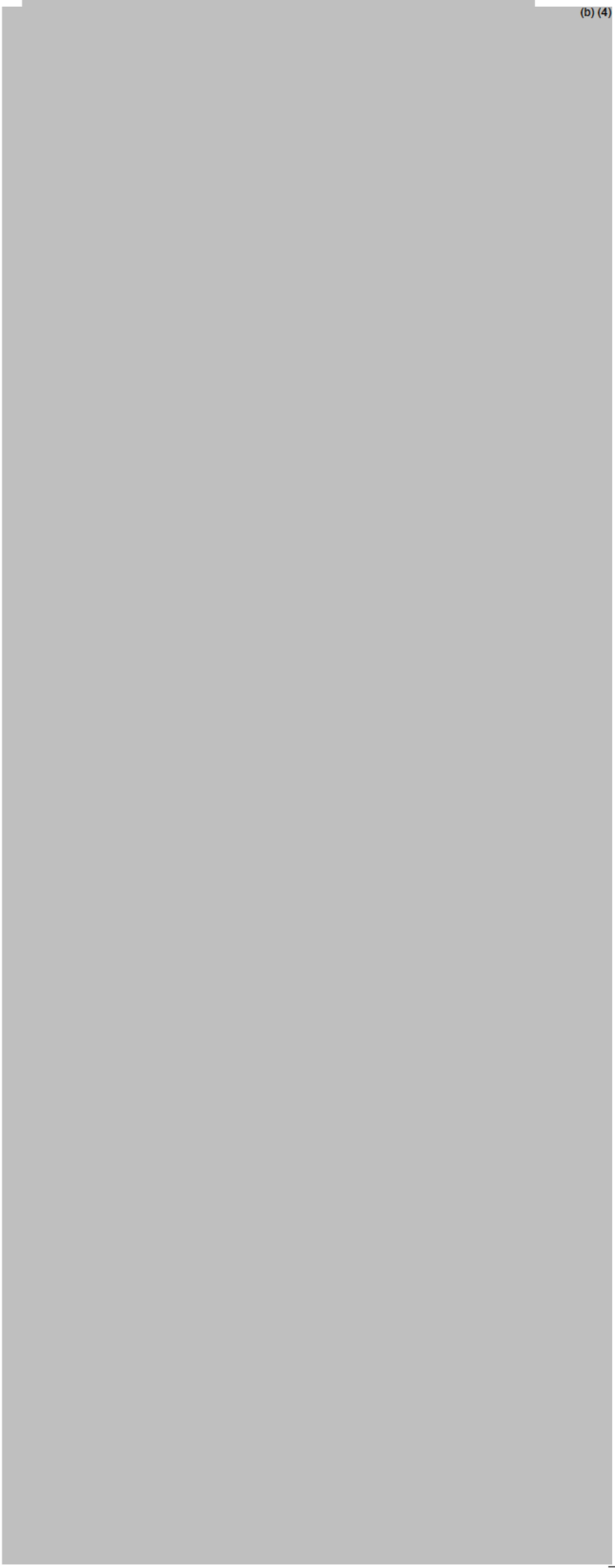
What are the Ingredients in Atorvastatin Calcium Tablets?
Active Ingredient: atorvastatin calcium
Inactive Ingredients: carboxymethylcellulose sodium, ferric oxide yellow, glycerin, magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate, talc, tromethamine.

℞ only
Manufactured in Slovenia by Lek Pharmaceuticals d.d,
for Sandoz Inc., Princeton, NJ 08540

Revised: March 2012

46082127


(b) (4)


(b) (4)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BETTY B TURNER
04/19/2012

CHI-ANN Y WU
04/20/2012
For Wm. Peter Rickman
Memo dated December 1, 2011 states drug substance meets USP monograph for atorvastatin calcium

LABELING APPROVAL SUMMARY

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 77575 Date of Submission: May 31, 2011

Applicant's Name: Sandoz Inc.

Established Name: Atorvastatin Calcium tablets 10 mg , 20 mg, 40 mg, 80 mg

---

REMS required?

MedGuides and/or PPIs (505-1(e))	☐ Yes	☒ No
Communication plan (505-1(e))	☐ Yes	☒ No
Elements to assure safe use (ETASU) (505-1(f)(3))	☐ Yes	☒ No
Implementation system if certain ETASU (505-1(f)(4))	☐ Yes	☒ No
Timetable for assessment (505-1(d))	☐ Yes	☒ No

ANDA REMS acceptable?
☐ Yes ☐ No ☒ n/a

APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? Yes,

Container Labels (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets) :
Final printed labels acceptable in 5/5/11 e-submission

Professional Package Insert Labeling: Final printed labeling acceptable in 5/5/11 e-submission

Patient Information Sheet: Final printed labeling acceptable in 5/5/11 e-submission

Revisions needed before full approval: No

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Lipitor

NDA Number: 20-702

NDA Drug Name: Lipitor

NDA Firm: Pfizer Inc.

Date of Approval of NDA Insert and supplement #: 20-702/S-056; approved 6/17/09.

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Note: The applicant\ is using an [redacted] form while the RLD has the trihydrate form.

NOTE TO CHEMIST: applicant use the [redacted] product with the RLD use the trihydrate product please let me know if there is a difference in the safety and efficacy of the different forms.

I emailed Gil Kang on December 8, 2010 to verify the [redacted] form vs. trihydrate form.

FOR THE RECORD: (parts of review based on B. Weitzman's LBL TA SUM)

1. MODEL LABELING This review was based on the labeling of the RLD, Lipitor, 20-702/S-056; approved 6/17/09: The PI is now in PLR format.

   Lek transfer of ownership to Sandoz per D. Doan's acknowledgement dated 8/16/10.

2. PATENTS/EXCLUSIVITIES: [Patent amendment dated 6/15/10]

Patent No	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
4681893	Sep. 24, 2009 PED. Mar. 24, 2010	U-161	method of treating hypercholesterolemia METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS IN A PATIENT	PIII	Same As
5273995	Dec 28, 2010 ped jun 28, 2011	u-162	METHOD OF USE TO INHIBIT CHOLESTEROL SYNTHESIS IN A HUMAN SUFFERING FROM HYPERCHOLESTEROLEMIA	PIII	Same As
5686104	Nov 11, 2014 ped May 11, 2015	U-213	METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS AND TREATING HYPERCHOLESTEROLEMIA AND METHOD FOR TREATING HYPERLIPIDEMIA	PIV	Same As
5969156	Jul 8, 2016 ped Jan 8, 2017	—		PIV	Same As
6126971	Jan 19, 2013 ped July 19, 2013	—		PIV	Same As
RE 40667	Jun 28, 2011*PED	U-162	Method of use to inhibit choletestrol synthesis in a human suffering from hypercholesterolemia	PIII	Same As

According to M. Holovac's email dated 12/6/10: Pfizer did NOT list the 7,790,197 patent yet.

3. MANUFACTURING FACILITY OF FINISHED DOSAGE FORM by Lek Pharmaceuticals d.d. at Verovskova 5, 1526 Ljubljana,Slovenia [Vol. A1.]

4. INACTIVE INGREDIENTS

   The description of the inactive ingredients in the insert labeling appears accurate according to the composition statement. [Vol. A1.1 pg. 106 and Vol. A1.2 pg. 532.] Atorvastatin Calcium Tablets contain atorvastatin and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified

Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine. The 80 mg give (b) (4) per tab elemental with ferric oxide being (b) (4) mg/tab

Per Chemist review #3 all of the tablets have less than (b) mg ferric oxide per tab, thus all tabs have less than 5 mg elemental iron per tab.

5. FINISHED DOSAGE FORM:

NDA: LIPITOR® (atorvastatin calcium) is supplied as white, elliptical, film-coated tablets of atorvastatin calcium containing 10, 20, 40 and 80 mg atorvastatin.
10 mg tablets: coded "PD 155" on one side and "10" on the other.
Bottles of 90 and 5000 and 10 x 10 unit dose blisters
20 mg tablets: coded "PD 156" on one side and "20" on the other. Bottles of 90 and 5000 and 10 x 10 unit dose blisters.
40 mg tablets: coded "PD 157" on one side and "40" on the other. Bottles of 90 and 500
80 mg tablets: coded "PD 158" on one side and "80" on the other. Bottles of 90 and 500

ANDA:
10 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 10" on one side
20 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 20" on one side
40 mg tablets Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 40" on one side
80 mg tablets Light yellow, dappled, glossy, **oval** biconvex film-coated tablet, debossed with "HLA 80" on one side

6. CONTAINER/CLOSURE: Section XIII of 5/31/11 e-submission

Product Strength	Fill Size (tablets)	Bottle (mL)	Cap (dimensions)	(b) (4)
10 mg and 20 mg	30s, 90s, 100s	(b) (4)	(b) (4)	
	1000			
	3000			
40 mg	30s, 90s, 100s			
	1000			
	2000			
80 mg	30s, 90s, 100s			
	1000			

In AF 5/31/11 e-submission, firm confirms that they are not launching the (b) (4)

6. PACKAGING

RLD: 90s, 100s (10 X 10) Unit Dose, or 500s and 5000s
ANDA: 10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets

7. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON
RLD: store at 25C(77F); excursions permitted to 15-30C (59-86F) [See USP CRT]. Keep tightly closed (protect from moisture). Protect from light.

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. (carton label)

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container. (container label)

8. DISPENSING STATEMENTS COMPARISON

NDA – Dispense in Well closed containers (USP)

ANDA – Dispense in a tight, light-resistant container. (container label)

USP – The DS is pending compendial

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at room temperature.

9. BIOAVAILABILITY/BIOEQUIVALENCE: the firm uses the [redacted] (b) (4) form rather than the trihydrate

As of December 8, 2010, DBE has no further questions per G. Li's review dated 5/7/2010.

10. CONTAINER LABELS:









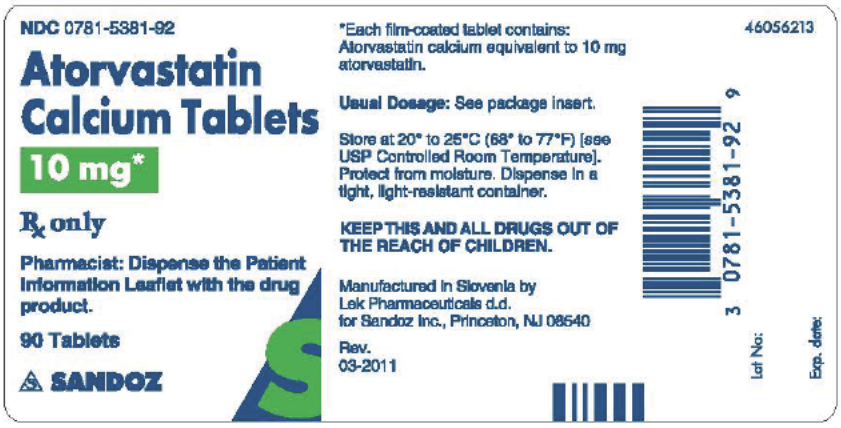
Date of Review: June 9, 2011 **Date of Submission: May 31, 2011**

Primary Reviewer: Thuyanh Vu **Date:**

Team Leader: John Grace **Date:**

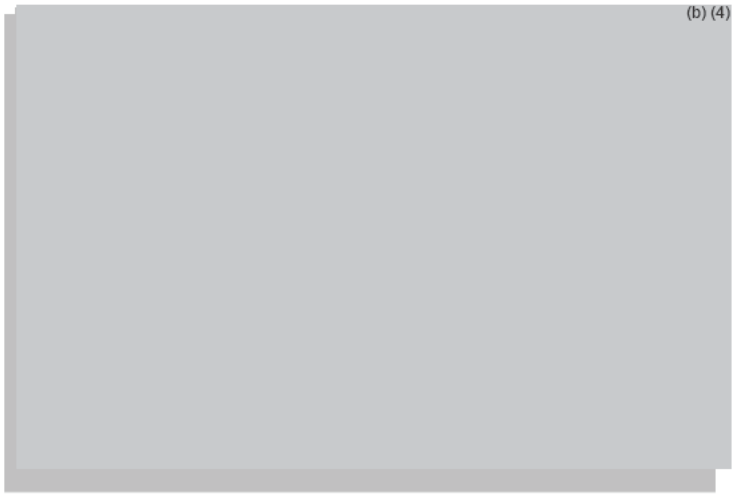

NDC 0781-5381-31
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056212
3 0781-5381-31 8
Lot No:
Exp. date:


(b) (4)


NDC 0781-5381-92
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056213
3 0781-5381-92 9
Lot No:
Exp. date:


(b) (4)


NDC 0781-5381-01
Atorvastatin Calcium Tablets
10 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
100 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056214
3 0781-5381-01 1
Lot No:
Exp. date:


(b) (4)

NDC 0781-5381-10

Atorvastatin Calcium Tablets

10 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
10 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5381-10 3

Lot No:

Exp. date:

46056215

(b) (4)

NDC 0781-5381-34

Atorvastatin Calcium Tablets

10 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

3000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
10 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5381-34 9

Lot No:

Exp. date:

46056216

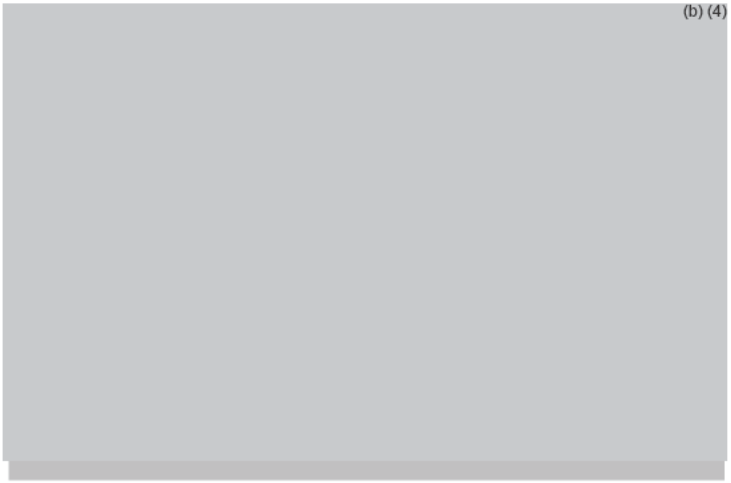
(b) (4)




NDC 0781-5382-31
Atorvastatin Calcium Tablets
20 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 20 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056217
3 0781-5382-31 5
Lot No:
Exp. date:

(b) (4)


NDC 0781-5382-92
Atorvastatin Calcium Tablets
20 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 20 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056218
3 0781-5382-92 6
Lot No:
Exp. date:


(b) (4)



(b) (4)

Additional demands:

NDC 0781-5382-10

Atorvastatin Calcium Tablets

20 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
20 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5382-10 0

Lot No:

Exp. date:

46056220

(b) (4)

NDC 0781-5382-34

Atorvastatin Calcium Tablets

20 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

3000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
20 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5382-34 6

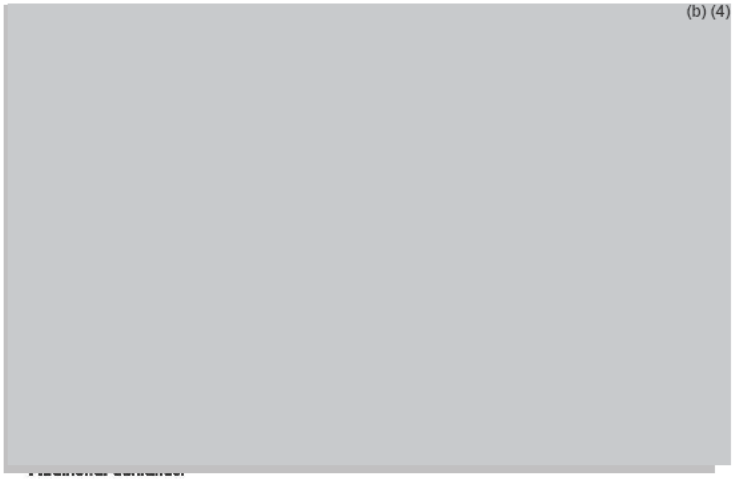
Lot No:

Exp. date:

46056221

(b) (4)

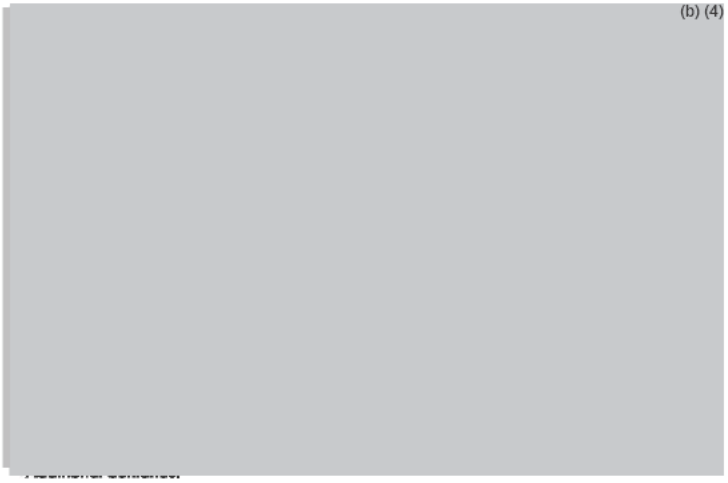

NDC 0781-5384-31
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540
Rev.
03-2011
46056222
3 0781-5384-31 9
Lot No:
Exp. date:


(b) (4)


NDC 0781-5384-92
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
90 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056223
3 0781-5384-92 0
Lot No:
Exp. date:

(b) (4)


NDC 0781-5384-01
Atorvastatin Calcium Tablets
40 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
100 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 40 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056224
3 0781-5384-01 2
Lot No:
Exp. date:


(b) (4)

NDC 0781-5384-10

Atorvastatin Calcium Tablets

40 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
40 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5384-10 4

46056225

Lot No:

Exp. date:

(b) (4)

NDC 0781-5384-22

Atorvastatin Calcium Tablets

40 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

2000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
40 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5384-22 7

46056226

Lot No:

Exp. date:

(b) (4)


NDC 0781-5388-31
Atorvastatin Calcium Tablets
80 mg*
℞ only
Pharmacist: Dispense the Patient Information Leaflet with the drug product.
30 Tablets
SANDOZ
*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Slovenia by Lek Pharmaceuticals d.d. for Sandoz Inc., Princeton, NJ 08540
Rev. 03-2011
46056227
3 0781-5388-31 7
Lot No:
Exp. date:


(b) (4)

NDC 0781-5388-92

Atorvastatin Calcium Tablets

80 mg*

℞ only

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

90 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

46056228

3 0781-5388-92 8

Lot No:

Exp. date:

(b) (4)

NDC 0781-5388-01

Atorvastatin Calcium Tablets

80 mg*

Rx only

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

100 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

46056229

3 0781-5388-01 0

Lot No:

Exp. date:

(b) (4)

NDC 0781-5388-10

Atorvastatin Calcium Tablets

80 mg*

℞ only

This package is not intended for dispensing.

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

1000 Tablets

SANDOZ

*Each film-coated tablet contains:
Atorvastatin calcium equivalent to
80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Rev.
03-2011

3 0781-5388-10 2

46056230

Lot No:

Exp. date:

(b) (4)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Atorvastatin Calcium Tablets safely and effectively. See full prescribing information for Atorvastatin Calcium Tablets.

Atorvastatin Calcium Tablets for oral administration
Initial U.S. Approval: 1996

----------INDICATIONS AND USAGE----------
Atorvastatin calcium tablet is an inhibitor of HMG-CoA reductase (statin) indicated as an adjunct therapy to diet to:
- Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without CHD, but with multiple risk factors (1.1).
- Reduce the risk of MI and stroke in patients with type 2 diabetes without CHD, but with multiple risk factors (1.1).
- Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in patients with CHD (1.1).
- Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (1.2).
- Reduce elevated TG in patients with hypertriglyceridemia and primary dysbetalipoproteinemia (1.2).
- Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) (1.2).
- Reduce elevated total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy (1.2).

Limitations of Use
Atorvastatin calcium tablets have not been studied in *Fredrickson* Types I and V dyslipidemias.

----------DOSAGE AND ADMINISTRATION----------
Dose range: 10 to 80 mg once daily (2.1).
Recommended start dose: 10 or 20 mg once daily (2.1).
Patients requiring large LDL-C reduction (>45%) may start at 40 mg once daily (2.1).
Pediatric starting dose: 10 mg once daily; maximum recommended dose: 20 mg once daily (2.2).

----------DOSAGE FORMS AND STRENGTHS----------
10, 20, 40, and 80 mg tablets (3).

----------CONTRAINDICATIONS----------
Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels (4.1).
Women who are pregnant or may become pregnant (4.3).
Nursing mothers (4.4).

FULL PRESCRIBING INFORMATION: CONTENTS*

1. INDICATIONS AND USAGE
1.1 Prevention of Cardiovascular Disease
1.2 Hyperlipidemia
1.3 Limitations of Use
2. DOSAGE AND ADMINISTRATION
2.1 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (*Fredrickson* Types IIa and IIb)
2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10 to 17 years of age)
2.3 Homozygous Familial Hypercholesterolemia
2.4 Concomitant Lipid-Lowering Therapy
2.5 Dosage in Patients With Renal Impairment
2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or a Combination of Ritonavir plus Saquinavir or Lopinavir plus Ritonavir
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
4.1 Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels
4.2 Hypersensitivity to any component of this medication
4.3 Pregnancy
4.4 Nursing mothers
5 WARNINGS AND PRECAUTIONS
5.1 Skeletal Muscle
5.2 Liver Dysfunction
5.3 Endocrine Function
5.4 CNS Toxicity
5.5 Use in Patients with Recent Stroke or TIA
6 ADVERSE REACTIONS
6.1 Clinical Trial Adverse Experiences
6.2 Postmarketing Experience
6.3 Pediatric Patients (ages 10 to 17 years)
7 DRUG INTERACTIONS
7.1 Strong Inhibitors of Cytochrome P450 3A4
Clarithromycin
Combination of Protease Inhibitors
Itraconazole
7.2 Grapefruit Juice
7.3 Cyclosporine
7.4 Rifampin or other Inducers of Cytochrome P450 3A4
7.5 Digoxin
7.6 Oral Contraceptives
7.7 Warfarin
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Hepatic Impairment
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Prevention of Cardiovascular Disease
14.2 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia (*Fredrickson* Types IIa and IIb)
14.3 Hypertriglyceridemia (*Fredrickson* Type IV)
14.4 Dysbetalipoproteinemia (Fredrickson Type III)
14.5 Homozygous Familial Hypercholesterolemia
14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
17.1 Muscle Pain
17.2 Liver Enzymes
17.3 Pregnancy
17.4 Breastfeeding

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE
Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, atorvastatin calcium tablets can be started simultaneously with diet.

1.1 Prevention of Cardiovascular Disease
In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin calcium tablets are indicated to:
- Reduce the risk of myocardial infarction
- Reduce the risk of stroke
- Reduce the risk for revascularization procedures and angina

In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin calcium tablets are indicated to:
- Reduce the risk of myocardial infarction
- Reduce the risk of stroke

In patients with clinically evident coronary heart disease, atorvastatin calcium tablets are indicated to:
- Reduce the risk of non-fatal myocardial infarction
- Reduce the risk of fatal and non-fatal stroke
- Reduce the risk for revascularization procedures
- Reduce the risk of hospitalization for CHF
- Reduce the risk of angina

1.2 Hyperlipidemia
Atorvastatin calcium tablets are indicated:
- As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilia) and mixed dyslipidemia *(Fredrickson* Types IIa and IIb);
- As an adjunct to diet for the treatment of patients with elevated serum TG levels *(Fredrickson* Type IV);
- For the treatment of patients with primary dysbetalipoproteinemia *(Fredrickson* Type III) who do not respond adequately to diet;
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable;
- As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
  a. LDL-C remains ≥ 190 mg/dL or
  b. LDL-C remains ≥ 160 mg/dL and:
     - there is a positive family history of premature cardiovascular disease or
     - two or more other CVD risk factors are present in the ped atric patient

1.3 Limitations of Use
Atorvastatin calcium tablets have not been studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons *(Fredrickson* Types I and V).

2. DOSAGE AND ADMINISTRATION
2.1 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia *(Fredrickson* Types IIa and IIb)
The recommended starting dose of atorvastatin calcium tablets is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily. The dosage range of atorvastatin calcium tablets is 10 to 80 mg once daily. Atorvastatin calcium tablets can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses of atorvastatin calcium tablets should be individualized according to patient characteristics such as goal of therapy and response (see current *NCEP Guidelines*). After initiation and/or upon titration of atorvastatin calcium tablets, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.

2.2 Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10 to 17 years of age)
The recommended starting dose of atorvastatin calcium tablets is 10 mg/ day; the maximum recommended dose is 20 mg/day (doses greater than 20 mg have not been studied in this patient population). Doses should be individualized according to the recommended goal of therapy [see current *NCEP Pediatric Panel Guidelines*, **CLINICAL PHARMACOLOGY (12)**, and **INDICATIONS AND USAGE (1.2)**]. Adjustments should be made at intervals of 4 weeks or more.

2.3 Homozygous Familial Hypercholesterolemia
The dosage of atorvastatin calcium tablets in patients with homozygous FH is 10 to 80 mg daily. Atorvastatin calcium tablets should be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

2.4 Concomitant Lipid-Lowering Therapy
Atorvastatin calcium tablets may be used with bile acid resins. The combination of HMG-CoA reductase inhibitors (statins) and fibrates should generally be used with caution [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), DRUG INTERACTIONS (7)**].

2.5 Dosage in Patients With Renal Impairment
Renal disease does not affect the plasma concentrations nor LDL-C reduction of atorvastatin calcium tablets; thus, dosage adjustment in patients with renal dysfunction is not necessary [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), CLINICAL PHARMACOLOGY, Pharmacokinetics (12.3)**].

2.6 Dosage in Patients Taking Cyclosporine, Clarithromycin, Itraconazole, or a Combination of Ritonavir plus Saquinavir or Lopinavir plus Ritonavir
In patients taking cyclosporine, therapy should be limited to atorvastatin calcium tablets 10 mg once daily. In patients taking clarithromycin, itraconazole, or in patients with HIV taking a combination of ritonavir plus saquinavir or lopinavir plus ritonavir, for doses of atorvastatin calcium tablets exceeding 20 mg, appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin calcium tablets is employed [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1), DRUG INTERACTIONS (7)**].

3 DOSAGE FORMS AND STRENGTHS
Light yellow, dappled, glossy, round biconvex, film-coated tablets containing 10, 20, and 40 mg atorvastatin calcium.
Light yellow, dappled, glossy, oval biconvex, film-coated tablets containing 80 mg atorvastatin calcium.

4. CONTRAINDICATIONS
4.1 Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels

4.2 Hypersensitivity to any component of this medication

4.3 Pregnancy
Women who are pregnant or may become pregnant. Atorvastatin calcium may cause fetal harm when administered to a pregnant woman. Serum cholesterol and triglycerides increase during normal pregnancy, and cholesterol or cholesterol derivatives are essential for fetal development. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. There are no adequate and well-controlled studies of atorvastatin calcium use during pregnancy; however in rare reports, congenital anomalies were observed following intrauterine exposure to statins. In rat and rabbit animal reproduction studies, atorvastatin revealed no evidence of teratogenicity. ATORVASTATIN CALCIUM SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS. If the patient becomes pregnant while taking this drug, atorvastatin calcium should be discontinued immediately and the patient apprised of the potential hazard to the fetus [see **USE IN SPECIFIC POPULATIONS (8.1)**].

4.4 Nursing mothers
It is not known whether atorvastatin is excreted into human milk; however a small amount of another drug in this class does pass into breast milk. Because statins have the potential for serious adverse reactions in nursing infants, women who require atorvastatin calcium treatment should not breastfeed their infants [see **USE IN SPECIFIC POPULATIONS (8.3)**].

5. WARNINGS AND PRECAUTIONS
5.1 Skeletal Muscle
Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin calcium and with other drugs in this class. A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Such patients merit closer monitoring for skeletal muscle effects.

Atorvastatin, like other statins, occasionally causes myopathy, defined as muscle aches or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values >10 times ULN. The concomitant use of higher doses of atorvastatin with certain drugs such as cyclosporine and strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, and HIV protease inhibitors) increases the risk of myopathy/rhabdomyolysis.
Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever. Atorvastatin calcium therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

The risk of myopathy during treatment with drugs in this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, erythromycin, clarithromycin, combination of ritonavir plus saquinavir or lopinavir plus ritonavir, niacin, or azole antifungals. Physicians considering combined therapy with atorvastatin calcium and fibric acid derivatives, erythromycin, clarithromycin, a combination of ritonavir plus saquinavir or lopinavir plus ritonavir, immunosuppressive drugs, azole antifungals, or lipid-modifying doses of niacin should carefully weigh the potential benefits and risks and should carefully monitor patients for any signs or symptoms of muscle pain, tenderness, or weakness, particularly during the initial months of therapy and during any periods of upward dosage titration of either drug. Lower starting and maintenance doses of atorvastatin should be considered when taken concomitantly with the aforementioned drugs [see **DRUG INTERACTIONS (7)**]. Periodic creatine phosphokinase (CPK) determinations may be considered in such situations, but there is no assurance that such monitoring will prevent the occurrence of severe myopathy.

Prescribing recommendations for interacting agents are summarized in **Table 1** [see also **DOSAGE AND ADMINISTRATION (2.6), DRUG INTERACTIONS (7), CLINICAL PHARMACOLOGY (12.3)**].
Table 1. Drug Interactions Associated with Increased Risk of Myopathy/ Rhabdomyolysis

Interacting Agents	Prescribing Recommendations
Cyclosporine	Do not exceed 10 mg atorvastatin daily
Clarithromycin, itraconazole, HIV protease inhibitors (ritonavir plus saquinavir or lopinavir plus ritonavir)	Caution when exceeding doses > 20 mg atorvastatin daily. The lowest dose necessary should be used.
Digoxin: Patients should be monitored appropriately (7.5).	
Oral Contraceptives: Values for norethindrone and ethinyl estradiol may be increased (7.6).	
Rifampin should be simultaneously co-administered with atorvastatin calcium (7.4).	

----------USE IN SPECIFIC POPULATIONS----------
- Hepatic impairment: Plasma concentrations markedly increased in patients with chronic alcoholic liver disease (12.3).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2011

Atorvastatin calcium therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a major predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures).

5.2 Liver Dysfunction
Statins, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. **Persistent elevations (>3 times the upper limit of normal [ULN] occurring on 2 or more occasions) in serum transaminases occurred in 0.7% of patients who received atorvastatin calcium in clinical trials. The incidence of these abnormalities was 0.2%, 0.2%, 0.6%, and 2.3% for 10, 20, 40, and 80 mg, respectively.**
One patient in clinical trials developed jaundice. Increases in liver function tests (LFT) in other patients were not associated with jaundice or other clinical signs or symptoms. Upon dose reduction, drug interruption, or discontinuation, transaminase levels returned to or near pretreatment levels without sequelae. Eighteen of 30 patients with persistent LFT elevations continued treatment with a reduced dose of atorvastatin calcium.

It is recommended that liver function tests be performed prior to and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (e.g., semiannually) thereafter. Liver enzyme changes generally occur in the first 3 months of treatment with atorvastatin calcium. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. Should an increase in ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of atorvastatin calcium is recommended.
Atorvastatin calcium should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contraindications to the use of atorvastatin calcium [see **CONTRAINDICATIONS (4.1)**].

5.3 Endocrine Function
Statins interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. Clinical studies have shown that atorvastatin calcium does not reduce basal plasma cortisol concentration or impair adrenal reserve. The effects of statins on male fertility have not been studied in adequate numbers of patients. The effects, if any, on the pituitary-gonadal axis in premenopausal women are unknown. Caution should be exercised if a statin is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

5.4 CNS Toxicity
Brain hemorrhage was seen in a female dog treated for 3 months at 120 mg/kg/day. Brain hemorrhage and optic nerve vacuolation were seen in another female dog that was sacrificed in moribund condition after 11 weeks of escalating doses up to 280 mg/kg/day. The 120 mg/kg dose resulted in a systemic exposure approximately 16 times the human plasma area-under-the-curve (AUC, 0–24 hours) based on the maximum human dose of 80 mg/day. A single tonic convulsion was seen in each of 2 male dogs (one treated at 10 mg/kg/day and one at 120 mg/kg/day) in a 2-year study. No CNS lesions have been observed in mice after chronic treatment for up to 2 years at doses up to 400 mg/kg/day or in rats at doses up to 100 mg/kg/day. These doses were 6 to 11 times (mouse) and 8 to 16 times (rat) the human AUC (0–24) based on the maximum recommended human dose of 80 mg/day.

CNS vascular lesions, characterized by perivascular hemorrhages, edema, and mononuclear cell infiltration of perivascular spaces, have been observed in dogs treated with other members of this class. A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion at a dose that produced plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose.

5.5 Use in Patients with Recent Stroke or TIA
In a post-hoc analysis of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) study where atorvastatin calcium 80 mg vs. placebo was administered in 4,731 subjects without CHD who had a stroke or TIA within the preceding 6 months, a higher incidence of hemorrhagic stroke was seen in the atorvastatin calcium 80 mg group compared to placebo (55, 2.3% atorvastatin vs. 33, 1.4% placebo; HR: 1.68, 95% CI: 1.09, 2.59; p=0.0168). The incidence of fatal hemorrhagic stroke was similar across treatment groups (17 vs. 18 for the atorvastatin and placebo groups, respectively). The incidence of nonfatal hemorrhagic stroke was significantly higher in the atorvastatin group (38, 1.6%) as compared to the placebo group (16, 0.7%). Some baseline characteristics, including hemorrhagic and lacunar stroke on study entry, were associated with a higher incidence of hemorrhagic stroke in the atorvastatin group [see **ADVERSE REACTIONS (6.1)**].

6. ADVERSE REACTIONS
The following serious adverse reactions are discussed in greater detail in other sections of the label:
Rhabdomyolysis and myopathy [see **WARNINGS AND PRECAUTIONS (5.1)**]
Liver enzyme abnormalities [see **WARNINGS AND PRECAUTIONS (5.2)**]

6.1 Clinical Trial Adverse Experiences
Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the atorvastatin calcium placebo-controlled clinical trial database of 16,066 patients (8755 atorvastatin calcium vs. 7311 placebo; age range 10 to 93 years, 39% women, 91% Caucasians, 3% Blacks, 2% Asians, 4% other) with a median treatment duration of 53 weeks, 9.7% of patients on atorvastatin calcium and 9.5% of the patients on placebo discontinued due to adverse reactions regardless of causality. The five most common adverse reactions in patients treated with atorvastatin calcium that led to treatment discontinuation and occurred at a rate greater than placebo were: myalgia (0.7%), diarrhea (0.5%), nausea (0.4%), alanine aminotransferase increase (0.4%), and hepatic enzyme increase (0.4%).

The most commonly reported adverse reactions (incidence ≥ 2% and greater than placebo) regardless of causality, in patients treated with atorvastatin calcium in placebo controlled trials (n=8755) were: nasopharyngitis (8.3%), arthralgia (6.9%), diarrhea (6.8%), pain in extremity (6%), and urinary tract infection (5.7%).

Table 2 summarizes the frequency of clinical adverse reactions, regardless of causality, reported in ≥ 2% and at a rate greater than placebo in patients treated with atorvastatin calcium (n=8755), from seventeen placebo-controlled trials.
Table 2. Clinical adverse reactions occurring in ≥ 2% in patents treated with any dose of atorvastatin calcium and at an incidence greater than placebo regardless of causality (% of patients).

Adverse Reaction[a]	Any dose N=8755	10 mg N=3908	20 mg N=188	40 mg N=604	80 mg N=4055	Placebo N=7311
Nasopharyngitis	8.3	12.9	5.3	7	4.2	8.2
Arthralgia	6.9	8.9	11.7	10.6	4.3	6.5
Diarrhea	6.8	7.3	6.4	14.1	5.2	6.3
Pain in extremity	6	8.5	3.7	9.3	3.1	5.9
Urinary tract infection	5.7	6.9	6.4	8	4.1	5.6
Dyspepsia	4.7	5.9	3.2	6	3.3	4.3
Nausea	4	3.7	3.7	7.1	3.8	3.5
Musculoskeletal pain	3.8	5.2	3.2	5.1	2.3	3.6
Muscle Spasms	3.6	4.6	4.8	5.1	2.4	3
Myalgia	3.5	3.6	5.9	8.4	2.7	3.1
Insomnia	3	2.8	1.1	5.3	2.8	2.9
Pharyngolaryngeal pain	2.3	3.9	1.6	2.8	0.7	2.1

[a] Adverse Reaction ≥ 2% in any dose greater than placebo

Other adverse reactions reported in placebo-controlled studies include:
Body as a whole: malaise, pyrexia; *Digestive system:* abdominal discomfort, eructation, flatulence, hepatitis, cholestasis; *Musculoskeletal system:* musculoskeletal pain, muscle fatigue, neck pain, joint swelling; *Metabolic and nutritional system:* transaminases increase, liver function test abnormal, blood alkaline phosphatase increase, creatine phosphokinase increase, hyperglycemia; *Nervous system:* nightmare; *Respiratory system:* epistaxis; *Skin and appendages:* urticaria; *Special senses:* vision blurred, tinnitus; *Urogenital system:* white blood cells urine positive.

Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT)
In ASCOT [see **CLINICAL STUDIES (14.1)**] involving 10,305 participants (age range 40 to 80 years, 19% women; 94.6% Caucasians, 2.6% Africans, 1.5% South Asians, 1.3% mixed/other) treated with atorvastatin calcium 10 mg daily (n=5,168) or placebo (n=5,137), the safety and tolerability profile of the group treated with atorvastatin calcium was comparable to that of the group treated with placebo during a median of 3.3 years of follow-up.

Collaborative Atorvastatin Diabetes Study (CARDS)
In CARDS [see **CLINICAL STUDIES (14.1)**] involving 2,838 subjects (age range 39 to 77 years, 32% women; 94.3% Caucasians, 2.4% South Asians, 2.3% Afro-Caribbean, 1% other) with type 2 diabetes treated with atorvastatin calcium 10 mg daily (n=1,428) or placebo (n=1,410), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 3.9 years. No cases of rhabdomyolysis were reported.

Treating to New Targets Study (TNT)
In TNT [see **CLINICAL STUDIES (14.1)**] involving 10,001 subjects (age range 29 to 78 years, 19% women; 94.1% Caucasians, 2.9% Blacks, 1% Asians, 2% other) with clinically evident CHD treated with atorvastatin calcium 10 mg daily (n=5006) or atorvastatin calcium 80 mg daily (n=4995), there were more serious adverse reactions and discontinuations due to adverse reactions in the high-dose atorvastatin group (92, 1.8%; 497, 9.9%, respectively) as compared to the low-dose group (69, 1.4%; 404, 8.1%, respectively) during a median follow-up of 4.9 years. Persistent transaminase elevations (≥3 × ULN twice within 4 to 10 days) occurred in 62 (1.3%) individuals with atorvastatin 80 mg and in nine (0.2%) individuals with atorvastatin 10 mg. Elevations of CK (≥ 10 × ULN) were low overall, but were higher in the high-dose atorvastatin treatment group (13, 0.3%) compared to the low-dose atorvastatin group (6, 0.1%).

Incremental Decrease in Endpoints through Aggressive Lipid Lowering Study (IDEAL)
In IDEAL [see **CLINICAL STUDIES (14.1)**] involving 8,888 subjects (age range 26 to 80 years, 19% women; 99.3% Caucasians, 0.4% Asians, 0.3% Blacks, 0.04% other) treated with atorvastatin calcium 80 mg/day (n=4439) or simvastatin 20 to 40 mg daily (n=4449), there was no difference in the overall frequency of adverse reactions or serious adverse reactions between the treatment groups during a median follow-up of 4.8 years.

Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL)
In SPARCL involving 4731 subjects (age range 21 to 92 years, 40% women; 93.3% Caucasians, 3% Blacks, 0.6% Asians, 3.1% other) without clinically evident CHD but with a stroke or transient ischemic attack (TIA) within the previous 6 months treated with atorvastatin calcium 80 mg (n=2365) or placebo (n=2366) for a median follow-up of 4.9 years, there was a higher incidence of persistent hepatic transaminase elevations (≥ 3 × ULN twice within 4 to 10 days) in the atorvastatin group (0.9%) compared to placebo (0.1%). Elevations of CK (>10 × ULN) were rare, but were higher in the atorvastatin group (0.1%) compared to placebo (0%). Diabetes was reported as an adverse reaction in 144 subjects (6.1%) in the atorvastatin group and 89 subjects (3.8%) in the placebo group [see **WARNINGS AND PRECAUTIONS (5.5)**].

In a post-hoc analysis, atorvastatin calcium 80 mg reduced the incidence of ischemic stroke (218/2365, 9.2% vs. 274/2366, 11.6%) and increased the incidence of hemorrhagic stroke (55/2365, 2.3% vs. 33/2366, 1.4%) compared to placebo. The incidence of fatal hemorrhagic stroke was similar between groups (17 atorvastatin calcium vs. 18 placebo). The incidence of non-fatal hemorrhagic strokes was significantly greater in the atorvastatin group (38 non-fatal hemorrhagic strokes) as compared to the placebo group (16 non-fatal hemorrhagic strokes). Subjects who entered the study with a hemorrhagic stroke appeared to be at increased risk for hemorrhagic stroke [7 (16%) atorvastatin calcium vs. 2 (4%) placebo].

There were no significant differences between the treatment groups for all-cause mortality: 216 (9.1%) in the atorvastatin calcium 80 mg/day group vs. 211 (8.9%) in the placebo group. The proportions of subjects who experienced cardiovascular death were numerically smaller in the atorvastatin calcium 80 mg group (3.3%) than in the placebo group (4.1%). The proportions of subjects who experienced non-cardiovascular death were numerically larger in the atorvastatin calcium 80 mg group (5%) than in the placebo group (4%).

6.2 Postmarketing Experience
The following adverse reactions have been identified during postapproval use of atorvastatin calcium. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Adverse reactions associated with atorvastatin calcium therapy reported since market introduction, that are not listed above, regardless of causality assessment, include the following: anaphylaxis, angioneurotic edema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis), rhabdomyolysis, fatigue, tendon rupture, hepatic failure, dizziness, memory impairment, depression, and peripheral neuropathy.

6.3 Pediatric Patients (ages 10 to 17 years)
In a 26-week controlled study in boys and postmenarchal girls (n=140, 31% female; 92% Caucasians, 1.6% Blacks, 1.6% Asians, 4.8% other), the safety and tolerability profile of atorvastatin calcium 10 to 20 mg daily was generally similar to that of placebo [see **CLINICAL STUDIES (14.6)** and **USE IN SPECIAL POPULATIONS, Pediatric Use (8.4)**].

7. DRUG INTERACTIONS
The risk of myopathy during treatment with statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP 3A4 inhibitors (e.g., clarithromycin, HIV protease inhibitors, and itraconazole) [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **CLINICAL PHARMACOLOGY (12.3)**].

7.1 Strong Inhibitors of CYP 3A4
Atorvastatin calcium is metabolized by cytochrome P450 3A4. Concomitant administration of atorvastatin calcium with strong inhibitors of CYP 3A4 can lead to increases in plasma concentrations of atorvastatin. The extent of interaction and potentiation of effects depend on the variability of effect on CYP 3A4.

Clarithromycin
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 80 mg with clarithromycin (500 mg twice daily) compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking clarithromycin, caution should be used when the atorvastatin calcium dose exceeds 20 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Combination of Protease Inhibitors
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 40 mg with ritonavir plus saquinavir (400 mg twice daily) or atorvastatin calcium 20 mg with lopinavir plus ritonavir (400 mg + 100 mg twice daily) compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking HIV protease inhibitors, caution should be used when the atorvastatin calcium dose exceeds 20 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

Itraconazole
Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 40 mg and itraconazole 200 mg [see **CLINICAL PHARMACOLOGY (12.3)**]. Therefore, in patients taking itraconazole, caution should be used when the atorvastatin calcium dose exceeds 20 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)** and **DOSAGE AND ADMINISTRATION (2.6)**].

7.2 Grapefruit Juice
Contains one or more components that inhibit CYP 3A4 and can increase plasma concentrations of atorvastatin, especially with excessive grapefruit juice consumption (>1.2 liters per day).

7.3 Cyclosporine
Atorvastatin and atorvastatin-metabolites are substrates of the OATP1B1 transporter. Inhibitors of the OATP1B1 (e.g., cyclosporine) can increase the bioavailability of atorvastatin. Atorvastatin AUC was significantly increased with concomitant administration of atorvastatin calcium 10 mg and cyclosporine 5.2 mg/kg/day compared to that of atorvastatin calcium alone [see **CLINICAL PHARMACOLOGY (12.3)**]. In cases where co-administration of atorvastatin calcium with cyclosporine is necessary, the dose of atorvastatin calcium should not exceed 10 mg [see **WARNINGS AND PRECAUTIONS, Skeletal Muscle (5.1)**].

7.4 Rifampin or other Inducers of Cytochrome P450 3A4
Concomitant administration of atorvastatin calcium with inducers of cytochrome P450 3A4 (e.g., efavirenz, rifampin) can lead to variable reductions in plasma concentrations of atorvastatin. Due to the dual interaction mechanism of rifampin, simultaneous co-administration of atorvastatin calcium with rifampin is recommended, as delayed administration of atorvastatin calcium after administration of rifampin has been associated with a significant reduction in atorvastatin plasma concentrations.

7.5 Digoxin
When multiple doses of atorvastatin calcium and digoxin were coadministered, steady state plasma digoxin concentrations increased by approximately 20%. Patients taking digoxin should be monitored appropriately.

7.6 Oral Contraceptives
Co-administration of atorvastatin calcium and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol [see **CLINICAL PHARMACOLOGY (12.3)**]. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin calcium.

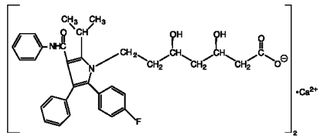
7.7 Warfarin
Atorvastatin calcium had no clinically significant effect on prothrombin time when administered to patients receiving chronic warfarin treatment.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category X
Atorvastatin calcium is contraindicated in women who are or may become pregnant. Serum cholesterol and triglycerides increase during normal pregnancy. Lipid lowering drugs offer no benefit during pregnancy because cholesterol and cholesterol derivatives are needed for normal fetal development. Atherosclerosis is a chronic process, and discontinuation of lipid-lowering drugs during pregnancy should have little impact on long-term outcomes of primary hypercholesterolemia therapy.

There are no adequate and well-controlled studies of atorvastatin use during pregnancy. There have been rare reports of congenital anomalies following intrauterine exposure to statins. In a review of about 100 prospectively followed pregnancies in women exposed to other statins, the incidences of congenital anomalies, spontaneous abortions, and fetal deaths/stillbirths did not exceed the rate expected in the general population. However, this study was only able to exclude a three-to-four-fold increased risk of congenital anomalies over background incidence. In 89% of these cases, drug treatment started before pregnancy and stopped during the first trimester when pregnancy was identified.

Atorvastatin crosses the rat placenta and reaches a level in fetal liver equivalent to that of maternal plasma. Atorvastatin was not teratogenic in rats at doses up to 300 mg/kg/day or in rabbits at doses up to 100 mg/kg/day. These doses resulted in multiples of about 30 times (rat) or 20 times (rabbit) the human exposure based on surface area (mg/m²) [see **CONTRAINDICATIONS, Pregnancy (4.3)**].

In a study in rats given 20, 100, or 225 mg/kg/day, from gestation day 7 through to lactation day 21 (weaning), there was decreased pup survival at birth, neonate, weaning, and maturity in pups of mothers dosed with 225 mg/kg/day. Body weight was decreased on days 4 and 21 in pups of mothers dosed at 100 mg/kg/day; pup body weight was decreased at birth and at days 4, 21, and 91 at 225 mg/kg/day. Pup development was delayed (rotorod performance at 100 mg/kg/day and acoustic startle at 225 mg/kg/day; pinnae detachment and eye-opening at 225 mg/kg/day). These doses correspond to 6 times (100 mg/kg) and 22 times (225 m



Atorvastatin calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile; slightly soluble in ethanol; and freely soluble in methanol.

Atorvastatin calcium tablets for oral administration contain 10, 20, 40, or 80 mg atorvastatin and the following inactive ingredients: carboxymethylcellulose sodium, ferric oxide yellow, glycerin, magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate, talc, tromethamine.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Atorvastatin calcium is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Cholesterol and triglycerides circulate in the bloodstream as part of lipoprotein complexes. With ultracentrifugation, these complexes separate into HDL (high-density lipoprotein), IDL (intermediate-density lipoprotein), LDL (low-density lipoprotein), and VLDL (very-low-density lipoprotein) fractions. Triglycerides (TG) and cholesterol in the liver are incorporated into VLDL and released into the plasma for delivery to peripheral tissues. LDL is formed from VLDL and is catabolized primarily through the high-affinity LDL receptor. Clinical and pathologic studies show that elevated plasma levels of total cholesterol (total-C), LDL-cholesterol (LDL-C), and apolipoprotein B (apo B) promote human atherosclerosis and are risk factors for developing cardiovascular disease, while increased levels of HDL-C are associated with a decreased cardiovascular risk.

In animal models, atorvastatin calcium lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL; atorvastatin calcium also reduces LDL production and the number of LDL particles. atorvastatin calcium reduces LDL-C in some patients with homozygous familial hypercholesterolemia (FH), a population that rarely responds to other lipid-lowering medication(s).

A variety of clinical studies have demonstrated that elevated levels of total-C, LDL-C, and apo B (a membrane complex for LDL-C) promote human atherosclerosis. Similarly, decreased levels of HDL-C (and its transport complex, apo A) are associated with the development of atherosclerosis. Epidemiologic investigations have established that cardiovascular morbidity and mortality vary directly with the level of total-C and LDL-C, and inversely with the level of HDL-C.

Atorvastatin calcium reduces total-C, LDL-C, and apo B in patients with homozygous and heterozygous FH, nonfamilial forms of hypercholesterolemia, and mixed dyslipidemia. Atorvastatin calcium also reduces VLDL-C and TG and produces variable increases in HDL-C and apolipoprotein A-1. Atorvastatin calcium reduces total-C, LDL-C, VLDL-C, apo B, TG, and non-HDL-C, and increases HDL-C in patients with isolated hypertriglyceridemia. Atorvastatin calcium reduces intermediate density lipoprotein cholesterol (IDL-C) in patients with dysbetalipoproteinemia.

Like LDL, cholesterol-enriched triglyceride-rich lipoproteins, including VLDL, intermediate density lipoprotein (IDL), and remnants, can also promote atherosclerosis. Elevated plasma triglycerides are frequently found in a triad with low HDL-C levels and small LDL particles, as well as in association with non-lipid metabolic risk factors for coronary heart disease. As such, total plasma TG has not consistently been shown to be an independent risk factor for CHD. Furthermore, the independent effect of raising HDL or lowering TG on the risk of coronary and cardiovascular morbidity and mortality has not been determined.

12.2 Pharmacodynamics

Atorvastatin calcium, as well as some of its metabolites, are pharmacologically active in humans. The liver is the primary site of action and the principal site of cholesterol synthesis and LDL clearance. Drug dosage, rather than systemic drug concentration, correlates better with LDL-C reduction. Individualization of drug dosage should be based on therapeutic response [see **DOSAGE AND ADMINISTRATION (2)**].

12.3 Pharmacokinetics

Absorption: Atorvastatin calcium is rapidly absorbed after oral administration; maximum plasma concentrations occur within 1 to 2 hours. Extent of absorption increases in proportion to atorvastatin calcium dose. The absolute bioavailability of atorvastatin (parent drug) is approximately 14% and the systemic availability of HMG-CoA reductase inhibitory activity is approximately 30%. The low systemic availability is attributed to presystemic clearance in gastrointestinal mucosa and/or hepatic first-pass metabolism. Although food decreases the rate and extent of drug absorption by approximately 25% and 9%, respectively, as assessed by C_{max} and AUC, LDL-C reduction is similar whether atorvastatin calcium is given with or without food. Plasma atorvastatin calcium concentrations are lower (approximately 30% for C_{max} and AUC) following evening drug administration compared with morning. However, LDL-C reduction is the same regardless of the time of day of drug administration [see **DOSAGE AND ADMINISTRATION (2)**].

Distribution: Mean volume of distribution of atorvastatin calcium is approximately 381 liters. Atorvastatin calcium is ≥98% bound to plasma proteins. A blood/plasma ratio of approximately 0.25 indicates poor drug penetration into red blood cells. Based on observations in rats, atorvastatin calcium is likely to be secreted in human milk [see **CONTRAINDICATIONS, Nursing Mothers (4.4)** and **USE IN SPECIFIC POPULATIONS, Nursing Mothers (8.3)**].

Metabolism: Atorvastatin calcium is extensively metabolized to ortho- and parahydroxylated derivatives and various beta-oxidation products. *In vitro* inhibition of HMG-CoA reductase by ortho- and parahydroxylated metabolites is equivalent to that of atorvastatin calcium. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites. *In vitro* studies suggest the importance of atorvastatin calcium metabolism by cytochrome P450 3A4, consistent with increased plasma concentrations of atorvastatin calcium in humans following co-administration with erythromycin, a known inhibitor of this isozyme [see **DRUG INTERACTIONS (7.1)**]. In animals, the ortho-hydroxy metabolite undergoes further glucuronidation.

Excretion: Atorvastatin calcium and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism; however, the drug does not appear to undergo enterohepatic recirculation. Mean plasma elimination half-life of atorvastatin calcium in humans is approximately 14 hours, but the half-life of inhibitory activity for HMG-CoA reductase is 20 to 30 hours due to the contribution of active metabolites. Less than 2% of a dose of atorvastatin calcium is recovered in urine following oral administration.

Specific Populations

Geriatric: Plasma concentrations of atorvastatin calcium are higher (approximately 40% for C_{max} and 30% for AUC) in healthy elderly subjects (age ≥65 years) than in young adults. Clinical data suggest a greater degree of LDL-lowering at any dose of drug in the elderly patient population compared to younger adults [see **USE IN SPECIFIC POPULATIONS, Geriatric Use (8.5)**].

Pediatric: Pharmacokinetic data in the pediatric population are not available.

Gender: Plasma concentrations of atorvastatin calcium in women differ from those in men (approximately 20% higher for C_{max} and 10% lower for AUC); however, there is no clinically significant difference in LDL-C reduction with atorvastatin calcium between men and women.

Renal Impairment: Renal disease has no influence on the plasma concentrations or LDL-C reduction of atorvastatin calcium; thus, dose adjustment in patients with renal dysfunction is not necessary [see **DOSAGE AND ADMINISTRATION, Dosage in Patients with Renal Impairment (2.5)**, **WARNINGS AND PRECAUTIONS**, *Skeletal Muscle (5.1)*].

Hemodialysis: While studies have not been conducted in patients with end-stage renal disease, hemodialysis is not expected to significantly enhance clearance of atorvastatin calcium since the drug is extensively bound to plasma proteins.

Hepatic Impairment: In patients with chronic alcoholic liver disease, plasma concentrations of atorvastatin calcium are markedly increased. C_{max} and AUC are each 4-fold greater in patients with Childs-Pugh A disease. C_{max} and AUC are approximately 16-fold and 11-fold increased, respectively, in patients with Childs-Pugh B disease [see **CONTRAINDICATIONS (4.1)**].

TABLE 3. Effect of Co-administered Drugs on the Pharmacokinetics of Atorvastatin

Co-administered drug and dosing regimen	Atorvastatin		
	Dose (mg)	Change in AUC[a]	Change in C_{max}[a]
[b]Cyclosporine 5.2 mg/kg/day, stable dose	10 mg QD for 28 days	↑ 8.7 fold	↑10.7 fold
[c]Lopinavir 400 mg BID/ritonavir 100 mg BID, 14 days	20 mg QD for 4 days	↑ 5.9 fold	↑ 4.7 fold
[c]Ritonavir 400 mg BID/saquinavir 400 mg BID, 15 days	40 mg QD for 4 days	↑ 3.9 fold	↑ 4.3 fold
[b]Clarithromycin 500 mg BID, 9 days	80 mg QD for 8 days	↑ 4.4 fold	↑ 5.4 fold
[b]Itraconazole 200 mg QD, 4 days	40 mg SD	↑ 3.3 fold	↑ 20%
[b]Grapefruit Juice, 240 mL QD [c]	40 mg, SD	↑ 37%	↑ 16%
Diltiazem 240 mg QD, 28 days	40 mg, SD	↑ 51%	No change
Erythromycin 500 mg QID, 7 days	10 mg, SD	↑ 33%	↑ 38%
Amlodipine 10 mg, single dose	80 mg, SD	↑ 15%	↓ 12 %
Cimetidine 300 mg QD, 4 weeks	10 mg QD for 2 weeks	↓ Less than 1%	↓ 11%
Colestipol 10 mg BID, 28 weeks	40 mg QD for 28 weeks	Not determined	↓ 26%[d]
Maalox TC® 30 mL QD, 17 days	10 mg QD for 15 days	↓ 33%	↓ 34%
Efavirenz 600 mg QD, 14 days	10 mg for 3 days	↓ 41%	↓ 1%
[b]Rifampin 600 mg QD, 7 days (co-administered) [e]	40 mg SD	↑ 30%	↑ 2.7 fold
[b]Rifampin 600 mg QD, 5 days (doses separated) [e]	40 mg SD	↓ 80%	↓ 40%
[b]Gemfibrozil 600 mg BID, 7 days	40 mg SD	↑ 35%	↓ Less than 1%
[b]Fenofibrate 160 mg QD, 7 days	40 mg SD	↑ 3%	↑ 2%

a) Data given as x-fold change represent a simple ratio between co administration and atorvastatin alone (i.e., 1-fold = no change). Data given as % change represent % difference relative to atorvastatin alone (i.e., 0% = no change).
b) See Sections 5.1 and 7 for clinical significance.
c) Greater increases in AUC (up to 2.5 fold) and/or C_{max} (up to 71%) have been reported with excessive grapefruit consumption (≥ 750 mL to 1.2 liters per day).
d) Single sample taken 8 to 16 h post dose.
e) Due to the dual interaction mechanism of rifampin, simultaneous co-administration of atorvastatin with rifampin is recommended, as delayed administration of atorvastatin after administration of rifampin has been associated with a significant reduction in atorvastatin plasma concentrations.

TABLE 4. Effect of Atorvastatin on the Pharmacokinetics of Co-administered Drugs

Atorvastatin	Co-administered drug and dosing regimen		
	Drug/Dose (mg)	Change in AUC	Change in C_{max}
80 mg QD for 15 days	Antipyrine, 600 mg SD	↑ 3%	↓ 11%
80 mg QD for 14 days	[a]Digoxin 0.25 mg QD, 20 days	↑ 15%	↑ 20 %
40 mg QD for 22 days	Oral contraceptive QD, 2 months - norethindrone 1 mg - ethinyl estradiol 35 mcg	↑ 28% ↑ 19%	↑ 23% ↑ 30%

a) See **Section 7** for clinical significance.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year carcinogenicity study in rats at dose levels of 10, 30, and 100 mg/kg/day, 2 rare tumors were found in muscle in high-dose females: in one, there was a rhabdomyosarcoma and, in another, there was a fibrosarcoma. This dose represents a plasma AUC (0–24) value of approximately 16 times the mean human plasma drug exposure after an 80 mg oral dose.

A 2-year carcinogenicity study in mice given 100, 200, or 400 mg/kg/day resulted in a significant increase in liver adenomas in high-dose males and liver carcinomas in high-dose females. These findings occurred at plasma AUC (0–24) values of approximately 6 times the mean human plasma drug exposure after an 80 mg oral dose.

In vitro, atorvastatin was not mutagenic or clastogenic in the following tests with and without metabolic activation: the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the HGPRT forward mutation assay in Chinese hamster lung cells, and the chromosomal aberration assay in Chinese hamster lung cells. Atorvastatin was negative in the *in vivo* mouse micronucleus test.

Studies in rats performed at doses up to 175 mg/kg (15 times the human exposure) produced no changes in fertility. There was aplasia and aspermia in the epididymis of 2 of 10 rats treated with 100 mg/kg/day of atorvastatin for 3 months (16 times the human AUC at the 80 mg dose); testis weights were significantly lower at 30 and 100 mg/kg and epididymal weight was lower at 100 mg/kg. Male rats given 100 mg/kg/day for 11 weeks prior to mating had decreased sperm motility, spermatid head concentration, and increased abnormal sperm. Atorvastatin caused no adverse effects on semen parameters, or reproductive organ histopathology in dogs given doses of 10, 40, or 120 mg/kg for two years.

14. CLINICAL STUDIES

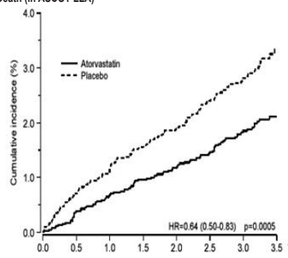
14.1 Prevention of Cardiovascular Disease

In the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), the effect of atorvastatin calcium on fatal and non-fatal coronary heart disease was assessed in 10,305 hypertensive patients 40 to 80 years of age (mean of 63 years), without a previous myocardial infarction and with TC levels ≤251 mg/dL (6.5 mmol/L). Additionally, all patients had at least 3 of the following cardiovascular risk factors: male gender (81.1%), age >55 years (84.5%), smoking (33.2%), diabetes (24.3%), history of CHD in a first-degree relative (26%), TC:HDL >6 (14.3%), peripheral vascular disease (5.1%), left ventricular hypertrophy (14.4%), prior cerebrovascular event (9.8%), specific ECG abnormality (14.3%), proteinuria/albuminuria (62.4%). In this double-blind, placebo-controlled study, patients were treated with anti-hypertensive therapy (Goal BP <140/90 mm Hg for non-diabetic patients; <130/80 mm Hg for diabetic patients) and allocated to either atorvastatin calcium 10 mg daily (n=5168) or placebo (n=5137), using a covariate adaptive method which took into account the distribution of nine baseline characteristics of patients already enrolled and minimized the imbalance of those characteristics across the groups. Patients were followed for a median duration of 3.3 years.

The effect of 10 mg/day of atorvastatin calcium on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of coronary events [either fatal coronary heart disease (46 events in the placebo group vs. 40 events in the atorvastatin calcium group) or non-fatal MI (108 events in the placebo group vs. 60 events in the atorvastatin calcium group)] with a relative risk reduction of 36% [(based on incidences of 1.9% for atorvastatin calcium vs. 3% for placebo), p=0.0005 (see **Figure 1**)]. The risk reduction was consistent regardless of age, smoking status, obesity, or presence of renal dysfunction. The effect of atorvastatin calcium was seen regardless of baseline LDL levels. Due to the small number of events, results for women were inconclusive.

Figure 1: Effect of Atorvastatin Calcium 10 mg/day on Cumulative Incidence of Non-Fatal Myocardial Infarction or Coronary Heart Disease Death (in ASCOT-LLA)



Atorvastatin calcium also significantly decreased the relative risk for revascularization procedures by 42%. Although the reduction of fatal and non-fatal strokes did not reach a pre-defined significance level (p=0.01), a favorable trend was observed with a 26% relative risk reduction (incidences of 1.7% for atorvastatin calcium and 2.3% for placebo). There was no significant difference between the treatment groups for death due to cardiovascular causes (p=0.51) or noncardiovascular causes (p=0.17).

In the Collaborative Atorvastatin Diabetes Study (CARDS), the effect of atorvastatin calcium on cardiovascular disease (CVD) endpoints was assessed in 2838 subjects (94% white, 68% male), ages 40 to 75 with type 2 diabetes based on WHO criteria, without prior history of cardiovascular disease and with LDL ≤ 160 mg/dL and TG ≤ 600 mg/dL. In addition to diabetes, subjects had 1 or more of the following risk factors: current smoking (23%), hypertension (80%), retinopathy (30%), or microalbuminuria (9%) or macroalbuminuria (3%). No subjects on hemodialysis were enrolled in the study. In this multicenter, placebo-controlled, double-blind clinical trial, subjects were randomly allocated to either atorvastatin calcium 10 mg daily (1429) or placebo (1411) in a 1:1 ratio and were followed for a median duration of 3.9 years. The primary endpoint was the occurrence of any of the major cardiovascular events: myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke. The primary analysis was the time to first occurrence of the primary endpoint.

Baseline characteristics of subjects were: mean age of 62 years, mean HbA_{1c} 7.7%; median LDL-C 120 mg/dL; median TC 207 mg/dL; median TG 151 mg/dL; median HDL-C 52 mg/dL.

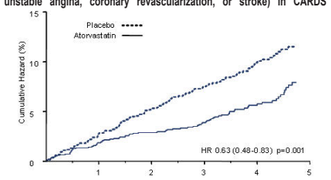
The effect of atorvastatin calcium 10 mg/day on lipid levels was similar to that seen in previous clinical trials.

Atorvastatin calcium significantly reduced the rate of major cardiovascular events (primary endpoint events) (83 events in the atorvastatin calcium group vs. 127 events in the placebo group) with a relative risk reduction of 37%, HR 0.63, 95% CI (0.48, 0.83) (p=0.001) (see **Figure 2**). An effect of atorvastatin calcium was seen regardless of age, sex, or baseline lipid levels.

Atorvastatin calcium significantly reduced the risk of stroke by 48% (21 events in the atorvastatin calcium group vs. 39 events in the placebo group), HR 0.52, 95% CI (0.31, 0.89) (p=0.016) and reduced the risk of MI by 42% (38 events in the atorvastatin calcium group vs. 64 events in the placebo group), HR 0.58, 95.1% CI (0.39, 0.86) (p=0.007). There was no significant difference between the treatment groups for angina, revascularization procedures, and acute CHD death.

There were 61 deaths in the atorvastatin calcium group vs. 82 deaths in the placebo group (HR 0.73, p=0.059).

Figure 2: Effect of Atorvastatin Calcium 10 mg/day on Time to Occurrence of Major Cardiovascular Event (myocardial infarction, acute CHD death, unstable angina, coronary revascularization, or stroke) in CARDS



In the Treating to New Targets Study (TNT), the effect of atorvastatin calcium 80 mg/day vs. atorvastatin calcium 10 mg/day on the reduction in cardiovascular events was assessed in 10,001 subjects (94% white, 81% male, 38% ≥65 years) with clinically evident coronary heart disease who had achieved a target LDL-C level <130 mg/dL after completing an 8-week, open-label, run-in period with atorvastatin calcium 10 mg/day. Subjects were randomly assigned to either 10 mg/day or 80 mg/day of atorvastatin calcium and followed for a median duration of 4.9 years. The primary endpoint was the time-to-first occurrence of any of the following major cardiovascular events (MCVE): death due to CHD, non-fatal myocardial infarction, resuscitated cardiac arrest, and fatal and non-fatal stroke. The mean LDL-C, TC, TG, non-HDL, and HDL cholesterol levels at 12 weeks were 73, 145, 128, 98, and 47 mg/dL during treatment with 80 mg of atorvastatin calcium and 99, 177, 152, 129, and 48 mg/dL during treatment with 10 mg of atorvastatin calcium.

Treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of MCVE (434 events in the 80 mg/day group vs. 548 events in the 10 mg/day group) with a relative risk reduction of 22%, HR 0.78, 95% CI (0.69, 0.89), p=0.0002 (see **Figure 3** and **Table 5**). The overall risk reduction was consistent regardless of age (<65, ≥65) or gender.

Figure 3: Effect of Atorvastatin Calcium 80 mg/day vs. 10 mg/day on Time to Occurrence of Major Cardiovascular Events (TNT)

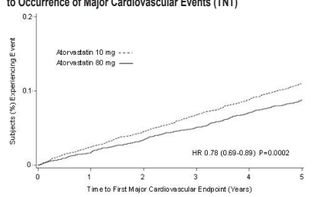


TABLE 5. Overview of Efficacy Results in TNT

Endpoint	Atorvastatin 10 mg (N=5006)		Atorvastatin 80 mg (N=4995)		HR[a] (95%CI)
PRIMARY ENDPOINT	n	(%)	n	(%)	
First major cardiovascular endpoint	548	(10.9)	434	(8.7)	0.78 (0.69, 0.89)
Components of the Primary Endpoint					
CHD death	127	(2.5)	101	(2)	0.80 (0.61, 1.03)
Non-fatal, non-procedure related MI	308	(6.2)	243	(4.9)	0.78 (0.66, 0.93)
Resuscitated cardiac arrest	26	(0.5)	25	(0.5)	0.96 (0.56, 1.67)
Stroke (fatal and non-fatal)	155	(3.1)	117	(2.3)	0.75 (0.59, 0.96)
SECONDARY ENDPOINTS[b]					
First CHF with hospitalization	164	(3.3)	122	(2.4)	0.74 (0.59, 0.94)
First PVD endpoint	282	(5.6)	275	(5.5)	0.97 (0.83, 1.15)
First CABG or other coronary revascularization procedure[c]	904	(18.1)	667	(13.4)	0.72 (0.65, 0.80)
First documented angina endpoint[c]	615	(12.3)	545	(10.9)	0.88 (0.79, 0.99)
All-cause mortality	282	(5.6)	284	(5.7)	1.01 (0.85, 1.19)
Components of All-Cause Mortality					
Cardiovascular death	155	(3.1)	126	(2.5)	0.81 (0.64, 1.03)
Noncardiovascular death	127	(2.5)	158	(3.2)	1.25 (0.99, 1.57)
Cancer death	75	(1.5)	85	(1.7)	1.13 (0.83, 1.55)
Other non-CV death	43	(0.9)	58	(1.2)	1.35 (0.91, 2)
Suicide, homicide, and other traumatic non-CV death	9	(0.2)	15	(0.3)	1.67 (0.73, 3.82)

HR=hazard ratio; CHD=coronary heart disease; CI=confidence interval; MI=myocardial infarction; CHF=congestive heart failure; CV=cardiovascular; PVD=peripheral vascular disease; CABG=coronary artery bypass graft
Confidence intervals for the Secondary Endpoints were not adjusted for multiple comparisons

a) Atorvastatin 80 mg: atorvastatin 10 mg
b) Secondary endpoints not included in primary endpoint
c) Component of other secondary endpoints

Of the events that comprised the primary efficacy endpoint, treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of non-fatal, non-procedure related MI and fatal and non-fatal stroke, but not CHD death or resuscitated cardiac arrest (**Table 5**). Of the predefined secondary endpoints, treatment with atorvastatin calcium 80 mg/day significantly reduced the rate of coronary revascularization, angina, and hospitalization for heart failure, but not peripheral vascular disease. The reduction in the rate of CHF with hospitalization was only observed in the 8% of patients with a prior history of CHF.

There was no significant difference between the treatment groups for all-cause mortality (**Table 5**). The proportions of subjects who experienced cardiovascular death, including the components of CHD death and fatal stroke, were numerically smaller in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group. The proportions of subjects who experienced noncardiovascular death were numerically larger in the atorvastatin calcium 80 mg group than in the atorvastatin calcium 10 mg treatment group.

In the Incremental Decrease in Endpoints Through Aggressive Lipid Lowering Study (IDEAL), treatment with atorvastatin calcium 80 mg/day was compared to treatment with simvastatin 20 to 40 mg/day in 8,888 subjects up to 80 years of age with a history of CHD to assess whether reduction in CV risk could be achieved. Patients were mainly male (81%), white (99%) with an average age of 61.7 years, and an average LDL-C of 121.5 mg/dL at randomization; 76% were on statin therapy. In this prospective, randomized, open-label, blinded endpoint (PROBE) trial with no run-in period, subjects were followed for a median duration of 4.8 years. The mean LDL-C, TC, TG, HDL, and non-HDL cholesterol levels at Week 12 were 78, 145, 115, 45, and 100 mg/dL during treatment with 80 mg of atorvastatin calcium and 105, 179, 142, 47, and 132 mg/dL during treatment with 20 to 40 mg of simvastatin.

There was no significant difference between the treatment groups for the primary endpoint, the rate of first major coronary event (fatal CHD, non-fatal MI, and resuscitated cardiac arrest): 411 (9.3%) in the atorvastatin calcium 80 mg/day group vs. 463 (10.4%) in the simvastatin 20 to 40 mg/day group, HR 0.89, 95% CI (0.78, 1.01), p=0.07.

There were no significant differences between the treatment groups for all-cause mortality: 366 (8.2%) in the atorvastatin calcium 80 mg/day group vs. 374 (8.4%) in the simvastatin 20 to 40 mg/day group. The proportions of subjects who experienced CV or non-CV death were similar for the atorvastatin calcium 80 mg group and the simvastatin 20 to 40 mg group.

14.2 Hyperlipidemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidemia *(Fredrickson* Types IIa and IIb)

Atorvastatin calcium reduces total-C, LDL-C, VLDL-C, apo B, and TG, and increases HDL-C in patients with hyperlipidemia and mixed dyslipidemia. Therapeutic response is seen within 2 weeks, and maximum response is usually achieved within 4 weeks and maintained during chronic therapy.

Atorvastatin calcium is effective in a wide variety of patient populations with hyperlipidemia, with and without hypertriglyceridemia, in men and women, and in the elderly.

In two multicenter, placebo-controlled, dose-response studies in patients with hyperlipidemia, atorvastatin calcium given as a single dose over 6 weeks, significantly reduced total-C, LDL-C, apo B, and TG. (Pooled results are provided in **Table 6**.)

TABLE 6. Dose Response in Patients With Primary Hyperlipidemia (Adjusted Mean % Change From Baseline)[a]

Dose	N	TC	LDL-C	Apo B	TG	HDL-C	Non-HDL-C/ HDL-C
Placebo	21	4	4	3	10	-3	7
10	22	-29	-39	-32	-19	6	-34
20	20	-33	-43	-35	-26	9	-41
40	21	-37	-50	-42	-29	6	-45
80	23	-45	-60	-50	-37	5	-53

a) Results are pooled from 2 dose-response studies.

In patients with *Fredrickson* Types IIa and IIb hyperlipoproteinemia pooled from 24 controlled trials, the median (25th and 75th percentile) percent changes from baseline in HDL-C for atorvastatin calcium 10, 20, 40, and 80 mg were 6.4 (-1.4, 14), 8.7 (0, 17), 7.8 (0, 16), and 5.1 (-2.7, 15), respectively. Additionally, analysis of the pooled data demonstrated consistent and significant decreases in total-C, LDL-C, TG, total-C/HDL-C, and LDL-C/HDL-C.

In three multicenter, double-blind studies in patients with hyperlipidemia, atorvastatin calcium was compared to other statins. After randomization, patients were treated for 16 weeks with either atorvastatin calcium 10 mg per day or a fixed dose of the comparative agent (**Table 7**).

TABLE 7. Mean Percentage Change From Baseline at Endpoint (Double-Blind, Randomized, Active-Controlled Trials)

Treatment (Daily Dose)	N	Total-C	LDL-C	Apo B	TG	HDL-C	Non-HDL-C/ HDL-C
Study 1							
Atorvastatin calcium 10 mg	707	-27[a]	-36[a]	-28[a]	-17[a]	+7	-37[a]
Lovastatin 20 mg	191	-19	-27	-20	-6	+7	-28
95% CI for Diff[b]		-9.2, -6.5	-10.7, -7.1	-10, -6.5	-15.2, -7.1	-1.7, 2	-11.1, -7.1
Study 2							
Atorvastatin calcium 10 mg	222	-25[c]	-35[c]	-27[c]	-17[c]	+6	-36[c]
Pravastatin 20 mg	77	-17	-23	-17	-9	+8	-28
95% CI for Diff[b]		-10.8, -6.1	-14.5, -8.2	-13.4, -7.4	-14.1, -0.7	-4.9, 1.6	-11.5, -4.1
Study 3							
Atorvastatin calcium 10 mg	132	-29[d]	-37[d]	-34[d]	-23[d]	+7	-39[d]
Simvastatin 10 mg	45	-24	-30	-30	-15	+7	-33
95% CI for Diff[b]		-8.7, -2.7	-10.1, -2.6	-8, -1.1	-15.1, -0.7	-4.3, 3.9	-9.6, -1.9

a) Significantly different from lovastatin, ANCOVA, p ≤0.05
b) A negative value for the 95% CI for the difference between treatments favors atorvastatin calcium for all except HDL-C, for which a positive value favors atorvastatin calcium. If the range does not include 0, this indicates a statistically significant difference.
c) Significantly different from pravastatin, ANCOVA, p ≤0.05
d) Significantly different from simvastatin, ANCOVA, p ≤0.05

The impact on clinical outcomes of the differences in lipid-altering effects between treatments shown in Table 7 is not known. Table 7 does not contain data comparing the effects of atorvastatin calcium 10 mg and higher doses of lovastatin, pravastatin, and simvastatin. The drugs compared in the studies summarized in the table are not necessarily interchangeable.

14.3 Hypertriglyceridemia *(Fredrickson* Type IV)

The response to atorvastatin calcium in 64 patients with isolated hypertriglyceridemia treated across several clinical trials is shown in the table below (**Table 8**). For the atorvastatin calcium-treated patients, median (min, max) baseline TG level was 565 (267 to 1502).

TABLE 8. Combined Patients With Isolated Elevated TG: Median (min, max) Percentage Change From Baseline

	Placebo (N=12)	Atorvastatin calcium 10 mg (N=37)	Atorvastatin calcium 20 mg (N=13)	Atorvastatin calcium 80 mg (N=14)
Triglycerides	-12.4 (-36.6, 82.7)	-41 (-76.2, 49.4)	-38.7 (-62.7, 29.5)	-51.8 (-82.8, 41.3)
Total-C	-2.3 (-15.5, 24.4)	-28.2 (-44.9, -6.8)	-34.9 (-49.6, -15.2)	-44.4 (-63.5, -3.8)
LDL-C	3.6 (-31.3, 31.6)	-26.5 (-57.7, 9.8)	-30.4 (-53.9, 0.3)	-40.5 (-60.6, -13.8)
HDL-C	3.8 (-18.6, 13.4)	13.8 (-9.7, 61.5)	11 (-3.2, 25.2)	7.5 (-10.8, 37.2)
VLDL-C	-1 (-31.9, 53.2)	-48.8 (-85.8, 57.3)	-44.6 (-62.2, -10.8)	-62 (-88.2, 37.6)
non-HDL-C	-2.8 (-17.6, 30)	-33 (-52.1, -13.3)	-42.7 (-53.7, -17.4)	-51.5 (-72.9, -4.3)

14.4 Dysbetalipoproteinemia *(Fredrickson* Type III)

The results of an open-label crossover study of 16 patients (genotypes: 14 apo E2/E2 and 2 apo E3/E2) with dysbetalipoproteinemia *(Fredrickson* Type III) are shown in the table below (**Table 9**).

TABLE 9. Open-Label Crossover Study of 16 Patients With Dysbetalipoproteinemia (*Fredrickson* Type III)

		Median % Change (min, max)	
	Median (min, max) at Baseline (mg/dL)	Atorvastatin Calcium 10 mg	Atorvastatin Calcium 80 mg
Total-C	442 (225, 1320)	-37 (-85, 17)	-58 (-90, -31)
Triglycerides	678 (273, 5990)	-39 (-92, -8)	-53 (-95, -30)
IDL-C + VLDL-C	215 (111, 613)	-32 (-76, 9)	-63 (-90, -8)
non-HDL-C	411 (218, 1272)	-43 (-87, -19)	-64 (-92, -36)

14.5 Homozygous Familial Hypercholesterolemia

In a study without a concurrent control group, 29 patients ages 6 to 37 years with homozygous FH received maximum daily doses of 20 to 80 mg of atorvastatin calcium. The mean LDL-C reduction in this study was 18%. Twenty-five patients with a reduction in LDL-C had a mean response of 20% (range of 7% to 53%, median of 24%); the remaining 4 patients had 7% to 24% increases in LDL-C. Five of the 29 patients had absent LDL-receptor function. Of these, 2 patients also had a portacaval shunt and had no significant reduction in LDL-C. The remaining 3 receptor-negative patients had a mean LDL-C reduction of 22%.

14.6 Heterozygous Familial Hypercholesterolemia in Pediatric Patients

In a double-blind, placebo-controlled study followed by an open-label phase, 187 boys and postmenarchal girls 10 to 17 years of age (mean age 14.1 years) with heterozygous familial hypercholesterolemia (FH) or severe hypercholesterolemia, were randomized to atorvastatin calcium (n=140) or placebo (n=47) for 26 weeks and then all received atorvastatin calcium for 26 weeks. Inclusion in the study required 1) a baseline LDL-C level ≥ 190 mg/dL or 2) a baseline LDL-C level ≥ 160 mg/dL and positive family history of FH or documented premature cardiovascular disease in a first or second-degree relative. The mean baseline LDL-C value was 218.6 mg/dL (range: 138.5 to 385 mg/dL) in the atorvastatin calcium group compared to 230 mg/dL (range: 160 to 324.5 mg/dL) in the placebo group. The dosage of atorvastatin calcium (once daily) was 10 mg for the first 4 weeks and uptitrated to 20 mg if the LDL-C level was > 130 mg/dL. The number of atorvastatin calcium-treated patients who required uptitration to 20 mg after Week 4 during the double-blind phase was 80 (57.1%).

Atorvastatin calcium significantly decreased plasma levels of total-C, LDL-C, triglycerides, and apolipoprotein B during the 26-week double-blind phase (see **Table 10**).

TABLE 10. Lipid-altering Effects of Atorvastatin Calcium in Adolescent Boys and Girls with Heterozygous Familial Hypercholesterolemia or Severe Hypercholesterolemia (Mean Percentage Change From Baseline at Endpoint in Intention-to-Treat Population)

DOSAGE	N	Total-C	LDL-C	HDL-C	TG	Apolipoprotein B
Placebo	47	-1.5	-0.4	-1.9	1	0.7
Atorvastatin calcium	140	-31.4	-39.6	2.8	-12	-34

The mean achieved LDL-C value was 130.7 mg/dL (range: 70 to 242 mg/dL) in the atorvastatin calcium group compared to 228.5 mg/dL (range: 152 to 385 mg/dL) in the placebo group during the 26-week double-blind phase.

The safety and efficacy of doses above 20 mg have not been studied in controlled trials in children. The long-term efficacy of atorvastatin calcium therapy in childhood to reduce morbidity and mortality in adulthood has not been established.

15. REFERENCES

1 National Cholesterol Education Program (NCEP): Highlights of the Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents, *Pediatrics*. 89(3):495–501. 1992.

16. HOW SUPPLIED/STORAGE AND HANDLING

Atorvastatin calcium tablets are supplied as follows:

10 mg, light yellow, dappled, glossy, round biconvex film-coated tablets, debossed with "HLA 10" on one side. Bottles contain desiccant.
NDC 0781-5381-31, bottle of 30 tablets
NDC 0781-5381-92, bottle of 90 tablets
NDC 0781-5381-01, bottle of


(b) (4)

PATIENT INFORMATION

Atorvastatin Calcium Tablets

(150 Units)



46056028

PATIENT INFORMATION
Atorvastatin Calcium Tablets

Read the Patient Information that comes with atorvastatin calcium tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

If you have any questions about atorvastatin calcium tablets, ask your doctor or pharmacist.

What are Atorvastatin Calcium Tablets?
Atorvastatin calcium tablets are a prescription medicine that lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. Atorvastatin calcium tablets are for adults and children over 10 whose cholesterol does not come down enough with exercise and a low-fat diet alone.

Atorvastatin calcium tablets can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:
- age, smoking, high blood pressure, low HDL-C, heart disease in the family.

Atorvastatin calcium tablets can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:
- eye problems, kidney problems, smoking, or high blood pressure.

Atorvastatin calcium tablets start to work in about 2 weeks.

What is Cholesterol?
Cholesterol and triglycerides are fats that are made in your body. They are also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol and triglycerides can clog your blood vessels. It is especially important to lower your cholesterol if you have heart disease, smoke, have diabetes or high blood pressure, are older, or if heart disease starts early in your family.

Who Should Not Take Atorvastatin Calcium Tablets?
Do not take atorvastatin calcium tablets if you:
- are pregnant or think you may be pregnant, or are planning to become pregnant. Atorvastatin calcium tablets may harm your unborn baby. If you get pregnant, stop taking atorvastatin calcium tablets and call your doctor right away.
- are breast feeding**.** Atorvastatin calcium tablets can pass into your breast milk and may harm your baby.
- have liver problems.
- are allergic to atorvastatin calcium tablets or any of its ingredients. The active ingredient is atorvastatin. See the end of this leaflet for a complete list of ingredients in atorvastatin calcium tablets.

Atorvastatin calcium tablets have not been studied in children under 10 years of age.

Before You Start Atorvastatin Calcium Tablets
Tell your doctor if you:
- have muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have diabetes
- have a thyroid problem
- have kidney problems

Some medicines should not be taken with atorvastatin calcium tablets. Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects. Especially tell your doctor if you take medicines for:
- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS

Know all the medicines you take.

Keep a list of them with you to show your doctor and pharmacist.

How Should I Take Atorvastatin Calcium Tablets?
- Take atorvastatin calcium tablets exactly as prescribed by your doctor. Do not change your dose or stop atorvastatin calcium tablets without talking to your doctor. Your doctor may do blood tests to check your cholesterol levels during your treatment with atorvastatin calcium tablets. Your dose of atorvastatin calcium tablets may be changed based on these blood test results.
- Take atorvastatin calcium tablets each day at any time of day at about the same time each day. Atorvastatin calcium tablets can be taken with or without food. Don't break atorvastatin calcium tablets before taking.
- Your doctor should start you on a low-fat diet before giving you atorvastatin calcium tablets. Stay on this low-fat diet when you take atorvastatin calcium tablets.
- If you miss a dose of atorvastatin calcium tablets, take it as soon as you remember. Do not take atorvastatin calcium tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of atorvastatin calcium tablets at the same time.

- If you take too much atorvastatin calcium tablets or overdose, call your doctor or Poison Control Center right away. Or go to the nearest emergency room.

What Should I Avoid While Taking Atorvastatin Calcium Tablets?
- Talk to your doctor before you start any new medicines. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Atorvastatin calcium tablets and certain other medicines can interact causing serious side effects.
- Do not get pregnant. If you get pregnant, stop taking atorvastatin calcium tablets right away and call your doctor.

What are the Possible Side Effects of Atorvastatin Calcium Tablets?

Atorvastatin calcium tablets can cause serious side effects. These side effects have happened only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or atorvastatin calcium tablets is stopped. These serious side effects include:

- **Muscle problems.** Atorvastatin calcium tablets can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with atorvastatin calcium tablets.
- **Liver problems.** Atorvastatin calcium tablets can cause liver problems. Your doctor may do blood tests to check your liver before you start taking atorvastatin calcium tablets, and while you take it.

Call your doctor right away if you have:
- muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual.
- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- nausea and vomiting.
- passing brown or dark-colored urine.
- you feel more tired than usual
- your skin and whites of your eyes get yellow.
- stomach pain.
- allergic skin reactions.

In clinical studies, patients reported the following common side effects while taking atorvastatin calcium tablets: diarrhea, upset stomach, muscle and joint pain, and alterations in some laboratory blood tests.

The following additional side effects have been reported with atorvastatin calcium tablets:
tiredness, and tendon problems.

Talk to your doctor or pharmacist if you have side effects that bother you or that will not go away.

These are not all the side effects of atorvastatin calcium tablets. Ask your doctor or pharmacist for a complete list.

How do I store Atorvastatin Calcium Tablets?

- Store atorvastatin calcium tablets at temperature 68° to 77°F (20° to 25°C).
- Do not keep medicine that is out of date or that you no longer need.
- **Keep atorvastatin calcium tablets and all medicines out of the reach of children.** Be sure that if you throw medicine away, it is out of the reach of children.

General Information About Atorvastatin Calcium Tablets
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use atorvastatin calcium tablets for a condition for which it was not prescribed. Do not give atorvastatin calcium tablets to other people, even if they have the same problem you have. It may harm them.
This leaflet summarizes the most important information about atorvastatin calcium tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about atorvastatin calcium tablets that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the Ingredients in Atorvastatin Calcium Tablets?
Active Ingredient: atorvastatin calcium
Inactive Ingredients: carboxymethylcellulose sodium, ferric oxide yellow, glycerin, magnesium stearate, pregelatinized starch, silicified microcrystalline cellulose, sodium lauryl sulfate, sodium starch glycolate, talc, tromethamine.

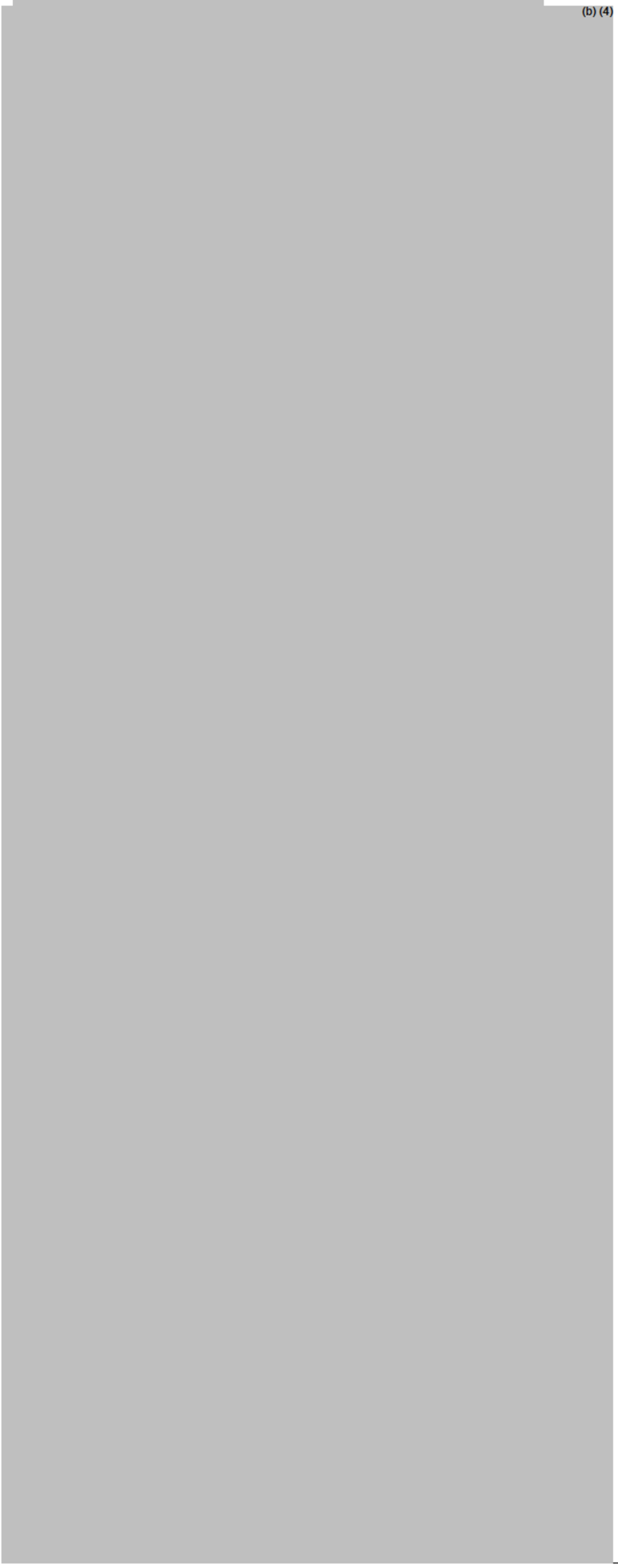
℞ only

Manufactured in Slovenia by Lek Pharmaceuticals d.d,
for Sandoz Inc., Princeton, NJ 08540

Revised: March 2011

46056028


(b) (4)


(b) (4)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THUYANH VU
06/09/2011

JOHN F GRACE
06/10/2011

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 77575 Date of Submission: November 22, 2010

Applicant's Name: Sandoz Inc.

Established Name: Atorvastatin Calcium tablets 10 mg , 20 mg, 40 mg, 80 mg

---

Labeling Deficiencies:

1. CONTAINER (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets)

   We note that you submitted container labels for 30s and 100s for all strengths. However, you did not submit pertinent chemistry information such as the container/closure and stability. Please submit chemistry data to both labeling and chemistry.

2. (b) (4)

3.

   Acceptable in final print.

4. INSERT

   FULL PRESCRIBING INFORMATION: CONTENTS*

   Revise to read:

   7 DRUG INTERACTIONS

   7.1 Strong Inhibitors of Cytochrome P450 3A4
   Clarithromycin
   Combination of Protease Inhibitors
   Itraconazole

5. PATIENT PACKAGE INSERT (PPI)

   Please state the number of sheets you intend on providing in order for each patient to receive one.

TENTATIVE APPROVAL SUMMARY (List the package size, strength(s), and date of submission for approval):

Do you have 12 Final Printed Labels and Labeling? No,

Container Labels (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets

(b) (4)

Professional Package Insert Labeling:

Patient Information Sheet:

Revisions needed before full approval: No

Was this approval based upon a petition? No

What is the RLD on the 356(h) form: Lipitor

NDA Number: 20-702

NDA Drug Name: Lipitor

NDA Firm: Pfizer Inc.

Date of Approval of NDA Insert and supplement #: 20-702/S-056; approved 6/17/09.

Has this been verified by the MIS system for the NDA? Yes

Was this approval based upon an OGD labeling guidance? No

Note: The applicant\ is using an (b) (4) form while the RLD has the trihydrate form.

NOTE TO CHEMIST: applicant use the (b) (4) product with the RLD use the trihydrate product please let me know if there is a difference in the safety and efficacy of the different forms.

I emailed Gil Kang on December 8, 2010 to verify the (b) (4) form vs. trihydrate form.

FOR THE RECORD: (parts of review based on B. Weitzman's LBL TA SUM)

1. MODEL LABELING This review was based on the labeling of the RLD, Lipitor, 20-702/S-056; approved 6/17/09: The PI is now in PLR format.

   Lek transfer of ownership to Sandoz per D. Doan's acknowledgement dated 8/16/10.

2. PATENTS/EXCLUSIVITIES: [Patent amendment dated 6/15/10]

Patent No	Patent Expiration	Use Code	Description	How Filed	Labeling Impact
4681893	Sep. 24, 2009 PED. Mar. 24, 2010	U-161	method of treating hypercholesterolemia METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS IN A PATIENT	PIII	Same As
5273995	Dec 28, 2010 ped jun 28, 2011	u-162	METHOD OF USE TO INHIBIT CHOLESTEROL SYNTHESIS IN A HUMAN SUFFERING FROM HYPERCHOLESTEROLEMIA	PIII	Same As
5686104	Nov 11, 2014 ped May 11, 2015	U-213	METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS AND TREATING	PIV	Same As

			HYPERCHOLESTEROLEMIA AND METHOD FOR TREATING HYPERLIPIDEMIA		
5969156	Jul 8, 2016 ped Jan 8, 2017	—		PIV	Same As
6126971	Jan 19, 2013 ped July 19, 2013	—		PIV	Same As
RE 40667	Jun 28, 2011*PED	U-162	Method of use to inhibit choletestrol synthesis in a human suffering from hypercholesterolemia	PIII	Same As

According to M. Holovac's email dated 12/6/10: Pfizer did NOT list the 7,790,197 patent yet.

3. MANUFACTURING FACILITY OF FINISHED DOSAGE FORM by Lek Pharmaceuticals d.d. at Verovskova 5, 1526 Ljubljana,Slovenia [Vol. A1.]

4. INACTIVE INGREDIENTS

The description of the inactive ingredients in the insert labeling appears accurate according to the composition statement. [Vol. A1.1 pg. 106 and Vol. A1.2 pg. 532.] Atorvastatin Calcium Tablets contain atorvastatin and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine. The 80 mg give (b) (6) per tab elemental with ferric oxide being (b) (6) mg/tab

Per Chemist review #3 all of the tablets have less than (b) (6) mg ferric oxide per tab, thus all tabs have less than 5 mg elemental iron per tab.

5. FINISHED DOSAGE FORM:

NDA: LIPITOR® (atorvastatin calcium) is supplied as white, elliptical, film-coated tablets of atorvastatin calcium containing 10, 20, 40 and 80 mg atorvastatin.
10 mg tablets: coded "PD 155" on one side and "10" on the other.
Bottles of 90 and 5000 and 10 x 10 unit dose blisters
20 mg tablets: coded "PD 156" on one side and "20" on the other. Bottles of 90 and 5000 and 10 x 10 unit dose blisters.
40 mg tablets: coded "PD 157" on one side and "40" on the other. Bottles of 90 and 500
80 mg tablets: coded "PD 158" on one side and "80" on the other. Bottles of 90 and 500

ANDA:
10 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 10" on one side
20 mg tablets: Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 20" on one side
40 mg tablets Light yellow, dappled, glossy, round biconvex film-coated tablet, debossed with "HLA 40" on one side
80 mg tablets Light yellow, dappled, glossy, **oval** biconvex film-coated tablet, debossed with "HLA 80" on one side

6. CONTAINER/CLOSURE:

Product Strength	Fill Size (tablets)	Bottle (mL)	Cap (dimensions)	(b) (4)
10 mg and 20 mg	90	(b) (4)	(b) (4	
	1000			
	3000			
40 mg	90			
	1000			

Product Strength	Fill Size (tablets)	Bottle (mL)	Cap (dimensions)	(b) (4)
	2000	(b) (4)	(b) (4)	
80 mg	90			
	1000			

Per chemist review #4, the 90 count are replaced from (b) (4)

In AF dated 11/22/10: Firm proposed new container size and (b) (4):

In addition to the above counts, Sandoz is also proposing the following new counts container labeling for Agency review.

10 mg: Bottles of 30 and 100 tablets
20 mg: Bottles of 30 and 100 tablets

40 mg: Bottles of 30 and 100 tablets
80 mg: Bottles of 30 and 100 tablets

(b) (4)



(b) (4)

(b) (4)

(b) (6)

7. STORAGE TEMPERATURE RECOMMENDATIONS COMPARISON
RLD: store at 25C(77F); excursions permitted to 15-30C (59-86F) [See USP CRT]. Keep tightly closed (protect from moisture). Protect from light.

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. (carton label)

ANDA: Store at 20 to 25C (68 to 77F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container. (container label)

8. DISPENSING STATEMENTS COMPARISON
NDA – Dispense in Well closed containers (USP)
ANDA – Dispense in a tight, light-resistant container. (container label)

USP – The DS is pending compendial
- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at room temperature.

9. BIOAVAILABILITY/BIOEQUIVALENCE: the firm uses the (b) (4) form rather than the trihydrate

As of December 8, 2010, DBE has no further questions per G. Li's review dated 5/7/2010.

10. CONTAINER LABELS:

NDC 0781-5381-31

Atorvastatin Calcium Tablets

10 mg*

℞ only

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

30 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 10 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d
for Sandoz Inc., Princeton, NJ 08540

Iss.
11-2010

Lot #
Exp. Date

0781-5381-31

NDC 0781-5382-31

Atorvastatin Calcium Tablets

20 mg*

℞ only

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

30 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 20 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d.
for Sandoz Inc., Princeton, NJ 08540

Iss.
11-2010

Lot #
Exp. Date

0781-5382-31

NDC 0781-5388-31

Atorvastatin Calcium Tablets

80 mg*

Pharmacist: Dispense the Patient Information Leaflet with the drug product.

℞ only

30 Tablets

SANDOZ

*Each film-coated tablet contains: Atorvastatin calcium equivalent to 80 mg atorvastatin.

Usual Dosage: See package insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight, light-resistant container.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured in Slovenia by
Lek Pharmaceuticals d.d
for Sandoz Inc., Princeton, NJ 08540

Rev.
11-2010

Lot #
Exp. Date

0781-5388-31



Date of Review: December 8, 2010 **Date of Submission:** November 22, 2010

Primary Reviewer: Thuyanh Vu **Date:**

Team Leader: John Grace **Date:**

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THUYANH VU
12/08/2010

JOHN F GRACE
12/13/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

CHEMISTRY REVIEWS

Addendum to the reviews in DARRTS dated 30-NOV-2011 and 01-DEC-2011

ANDA 077575

Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

Sandoz Inc.

(Ownership has been transferred to Sandoz Inc. from Lek Pharmaceuticals d.d.)

Gil-Jong Kang
Office of Generic Drugs
Division of Chemistry III
Team 31

Reference ID: 3132833

Chemistry Review Data Sheet

1. ANDA # 077575

2. REVIEW # 6_addendum

3. REVIEW DATE: 16-MAY-2012

4. REVIEWER: Gil-Jong Kang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	11-FEB-2005
Acceptable for filing	18-FEB-2005
Amendment (Telephone)	01-APR-2005
Correspondence (Change of US agent)	17-JUN-2005
Deficiency letter based on Review #1	31-AUG-2005
Pharm/Tox consult result (tromethamine)	03-OCT-2005
Minor amendment & Change of US agent	12-OCT-2005
Deficiency letter based on Review #2	13-MAR-2006
Minor amendment	02-OCT-2006
Deficiency letter based on Review #3	25-APR-2007
Minor amendment	26-SEP-2007
Correspondence (Transfer of ownership from Lek to Sandoz)	17-MAY-2010
Pharm/Tox consult review	26-AUG-2010 & 01-SEP-2010
Deficiency letter based on Review #4	27-SEP-2010
Major amendment (revised manufacturing process and new bio batch)	11-MAR-2009
Minor amendment (Response)	-
Pharm/Tox consult review	24-MAR-2011
Pharm/Tox consult review	04-MAY-2011
Telephone amendment/ Packaging changes	25-MAY-2011
Telephone amendment/ Packaging changes	14-JUN-2011
Telephone amendment/ Packaging changes	22-JUN-2011
Telephone amendment (Impurity)	13-JUL-2011
Review #5	30-AUG-2011
Telephone amendment	06-OCT-2011
Telephone amendment (IR identification test)	03-OCT-2011
	26-OCT-2011

Reference ID: 3132833

Method Validation Report	18-NOV-2011
Review #6	30-NOV-2011
Addendum to Review #6	01-DEC-2011

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Correspondence (Minor amendment)	27-APR-2012

7. NAME & ADDRESS OF APPLICANT:

Name: Sandoz Inc.

Address: 506 Carnegie Center
Suite 400
Princeton, NJ 08540

Representative: Bernadette Attinger

Telephone: (609) 627-8865
Fax: (609) 395-2792

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Atorvastatin Calcium Tablets

9. LEGAL BASIS FOR SUBMISSION:

Reference listed drug: Lipitor® Tablets
Pfizer
Application Number: N020702
Strength: 10 mg, 20 mg, 40 mg and 80 mg

Patent Certification:

Paragraph III Certification (p.13)

Paragraph IV Certification (p.14)

Lek certifies that to the best of its knowledge, U.S. patent Nos. 5,686,104; 5,969,156 and 6,126,971 which will expire on 11-MAY-2015, 08-JAN-2017 and 19-JUL, 2013, respectively are invalid or will not be infringed by the manufacture, use or sale of Lek product.

Lek will comply with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner, or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95(c) with respect to the contents of the notice.

Exclusivity statement:

The applicant does not seeking approval until after the date of expiry of the U. S. Patents No. 5,273,995 on 28-JUN-2011.

Exclusivity	Expiration

Reference ID: 3132833

Chemistry Review Data Sheet

D-77	22-APR-2005
M-36	30-JUL-2007
I-434	30-JUL-2007
I-350	18-OCT-2005
PED	18-APR-2006

10. PHARMACOL. CATEGORY:
Antihypercholesterolemic, inhibitor of HMG-CoA reductase.

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
10 mg, 20 mg, 40 mg, and 80 mg

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X_ Rx ___ OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
Atorvastatin Calcium
$(C_{33}H_{34}FN_2O_5)_2Ca$
CAS 134523-03-8

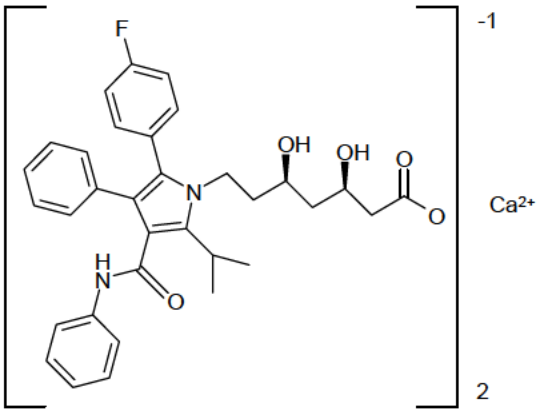
CAS 134523-00-5 (atorvastatin)

FW 2 x 557.7 + 40.0 = 1155.38

(b) (4)

1*H*-Pyrrole-heptanoic acid, 2-(4-fluorophenyl)-β,-δ-hydroxy-5-(methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-,calcium salt (2:1),[*R*-(*R**,*R**)]-

Reference ID: 3132833



17. RELATED/SUPPORTING DOCUMENTS

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
18082	II	Lek	Drug substance	3	Adequate	21-SEP-2011	Reviewed by G. Kang
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		USP test results are included.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	IV			4	N/A		
	III			4	N/A		
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		GRAS
	III			4	N/A		
DMF added in the amendment dated 11-MAR-2009.							
(b) (4) b) (4)	III	(b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 175.105, 170-199, 175-300.
	III			4	N/A		USP test results are included.
	III			4	N/A		Details on Page 108 (section XIII)
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21

							CFR 177.1520 (b) (4)

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	acceptable	09-MAY-2012	A. Inyard
Methods Validation	N/A		
Labeling	acceptable	20-APR-2012	B. Turner
Bioequivalence	Dissolution: acceptable* BE: acceptable	07-MAY-2010	X. Jiang L. Gong
EA	Waiver submitted		
Radiopharmaceutical	N/A		

* There is a "dissolution only" review (V:\firmsam\Lek\ltrs&rev\77575D0205.doc) and a "full ANDA" review (V:\firmsam\Lek\ltrs&rev\77575N0205.doc). As per the recommendation 3 on page the 12 of the "full ANDA" review, the firm has acknowledged the FDA-recommended method (900 ml of 0.05 M phosphate buffer pH 6.8 with paddles at 75 rpm) and specification [NLT (b) (4) (Q) in 15 minutes]. ------ Information taken from page 2 of 07-MAY-2010 Bio review (DARRTS).

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ____ Yes __X__ No If no, explain reason(s) below:

Correspondence

Reference ID: 3132833

The Chemistry Review for ANDA 077575

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

CMC section is **acceptable pending the note listed in II.C of this section.**

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

The reference listed drug for this application is Lipitor® Tablets 10 mg, 20, 30 mg and 40 mg by Pfizer. Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate limiting step in the biosynthesis of cholesterol.

Atorvastatin Calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin Calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Sandoz' Atorvastatin Calcium Tablets are manufactured using (b) (4) atorvastatin calcium whereas the Pfizer's Lipitor is manufactured using the crystalline atorvastatin calcium trihydrate.

Note: Drug substance meets the IR identification test under the modified <197K> conditions to the current USP monograph. The results have been confirmed by the Agency laboratories at St. Louis, Missouri. Therefore the Agency concludes that Sandoz' drug substance meet the USP monograph for the ID test per the API Sameness memorandum darrts dated Nov 30, 2011

There are references made to the USP pending monograph in the current review and earlier review cycles. However, referencing to pending monograph in the current and earlier review cycles has no impact on the satisfactory outcome for the drug substance per addendum darrts dated Nov 30, 2011.

Atorvastatin Calcium Tablets contain atorvastatin calcium and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium

Reference ID: 3132833

Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine.

The drug product is manufactured by [redacted] (b) (4)

Stability batches were packaged in each strength of the smallest and largest size of each marketed container/closure system. The firm submitted three months accelerated and room temperature stability data. The firm has requested 24 months expiration date based on the three months accelerated stability data.

New bio-batch:
The firm has manufactured new bio-batch (30004016/AA3869) and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired. These new batches were manufactured using revised manufacturing processes [redacted] (b) (4)

B. Description of How the Drug Product is Intended to be Used

Maximum Daily Dose is 80 mg/day as per Labeling insert information.
The drug substance: based on the ICH Guideline Q3A(R)
IT is 0.10% for any single unknown impurities (unspecified).
QT is 0.15% for any specified identified or specified unidentified impurity.

The drug product: based on the ICH Guideline Q3B(R)
IT is 0.20% for any single unknown impurities (unspecified).
QT is 0 (b) (4)% for any specified identified or specified unidentified impurity.

C. Basis for Approvability or Not-Approval Recommendation

CMC is acceptable pending the following note*.
Bio and labeling sections are acceptable.
EES is acceptable.

**Note: ANDA approvability is pending Division review, other disciplines and/or EES. This CMC review may require an addendum based on recommendations made by other review disciplines.*

Chemistry Assessment

Note: items 1 – 19 are now covered in the Chemistry Review Data Sheet and items 20 – 29 are covered in the previous review (Review #6 in Darrts dated 30-NOV-2011).

Sandoz has submitted a Minor amendment dated 27-APR-2012 to pending ANDA 077575 for the approval. In this amendment, Sandoz Inc. confirms that no changes have been made to the Chemistry, Manufacturing, and Controls (CMC) section since the last CMC telephone amendment submitted on October 26, 2011. ----- CMC section is approvable.

30. MICROBIOLOGY

Review Status: N/A

31. SAMPLES AND RESULTS/METHODS VALIDATION STATUS

Review Status: N/A

Samples of DS and DP will be available upon request (p.14272)

32. LABELING

Review Status: acceptable on 20-APR-2012.

33. ESTABLISHMENT INSPECTION

Review Status: acceptable on 09-MAY-2012.

34. BIOEQUIVALENCE

Review Status: acceptable on 07-MAY-2010.

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:

Review Status: satisfactory

A waiver was submitted on page 14274.

cc: ANDA 077575
ANDA DUP
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):

HFD-630/G. Kang, Ph.D./5/16/2012

HFD-630/L. Nagavelli, Ph.D., Team Leader/5/17/2012

HFD-617/Robert Gaines, Project Manager/5/18/12

V:\Chemistry Division III\Team 31\ANDA REVIEWS\Gil\77575RV6_addendum.doc

TYPE OF LETTER: APPROVABLE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
05/18/2012

LAXMA R NAGAVELLI
05/18/2012

ROBERT T GAINES
05/18/2012

Addendum

ANDA 077575 - Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, 80 mg Sandoz Inc.

There are references to the authorized pending USP drug substance monograph in the CMC reviews. This addendum is included to confirm that the atorvastatin calcium active ingredient in this application meets the standards of identity set forth in the current USP drug substance monograph for atorvastatin calcium.

Vilayat A. Sayeed, Ph.D.
Director, Division of Chemistry III

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VILAYAT A SAYEED
12/01/2011

ANDA 077575

Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

Sandoz Inc.

(Ownership has been transferred to Sandoz Inc. from Lek Pharmaceuticals d.d.)

Gil-Jong Kang
Office of Generic Drugs
Division of Chemistry III
Team 31

Table of Contents

Table of Contents **2**

Chemistry Review Data Sheet **3**

The Executive Summary **8**

I. Recommendations 8

A. Recommendation and Conclusion on Approvability 8

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable 8

II. Summary of Chemistry Assessments 8

A. Description of the Drug Product(s) and Drug Substance(s) 8

B. Description of How the Drug Product is Intended to be Used 9

C. Basis for Approvability or Not-Approval Recommendation 9

Chemistry Assessment (Part I) **10**

Chemistry Assessment (Part II) **47**

Chemistry Review Data Sheet

1. ANDA # 077575

2. REVIEW # 6

3. REVIEW DATE: 29-NOV-2011

4. REVIEWER: Gil-Jong Kang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	11-FEB-2005
Acceptable for filing	18-FEB-2005
Amendment (Telephone)	01-APR-2005
Correspondence (Change of US agent)	17-JUN-2005
Deficiency letter based on Review #1	31-AUG-2005
Pharm/Tox consult result (tromethamine)	03-OCT-2005
Minor amendment & Change of US agent	12-OCT-2005
Deficiency letter based on Review #2	13-MAR-2006
Minor amendment	02-OCT-2006
Deficiency letter based on Review #3	25-APR-2007
Minor amendment	26-SEP-2007
Correspondence (Transfer of ownership from Lek to Sandoz)	17-MAY-2010
Pharm/Tox consult review	26-AUG-2010 & 01-SEP-2010
Deficiency letter based on Review #4	27-SEP-2010
Major amendment (revised manufacturing process and new bio batch)	11-MAR-2009
Minor amendment (Response)	-
Pharm/Tox consult review	24-MAR-2011
Pharm/Tox consult review	04-MAY-2011
Telephone amendment/ Packaging changes	25-MAY-2011
Telephone amendment/ Packaging changes	14-JUN-2011
Telephone amendment/ Packaging changes	22-JUN-2011
Telephone amendment (Impurity)	13-JUL-2011
Review #5	30-AUG-2011
	06-OCT-2011

Reference ID: 3052070

Chemistry Review Data Sheet

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Telephone amendment	03-OCT-2011
Telephone amendment (IR identification test)	26-OCT-2011
Method Validation Report	18-NOV-2011

7. NAME & ADDRESS OF APPLICANT:

Name: Sandoz Inc.

Address: 506 Carnegie Center
Suite 400
Princeton, NJ 08540

Representative: Bernadette Attinger

Telephone: (609) 627-8865
Fax: (609) 395-2792

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Atorvastatin Calcium Tablets

9. LEGAL BASIS FOR SUBMISSION:

Reference listed drug: Lipitor® Tablets
Pfizer
Application Number: N020702
Strength: 10 mg, 20 mg, 40 mg and 80 mg

Patent Certification:

-Paragraph III Certification (p.13)

Sandoz certifies that, U.S. patent No. 4,681,893 will expire on 24-MAR-2010, and U.S. patent No. 5,273,995 will expire on 28-JUN-2011. Sandoz certifies that approval of the Lek product is sought to be effective upon expiration of both patents stated above.
Sandoz included a Paragraph III certification for US Patent No. RE40667 in patent amendment dated 15-JUN-2010

-Paragraph IV Certification (p.14)

Lek certifies that to the best of its knowledge, U.S. patent Nos. 5,686,104; 5,969,156 and 6,126,971 which will expire on 11-MAY-2015, 08-JAN-2017 and 19-JUL, 2013, respectively are invalid or will not be infringed by the manufacture, use or sale of Lek product.

Lek will comply with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner, or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95(c) with respect to the contents of the notice.

Reference ID: 3052070

Chemistry Review Data Sheet

Exclusivity statement:

The applicant does not seeking approval until after the date of expiry of the U. S. Patents No. 5,273,995 on 28-JUN-2011.

Exclusivity	Expiration
D-77	22-APR-2005
M-36	30-JUL-2007
I-434	30-JUL-2007
I-350	18-OCT-2005
PED	18-APR-2006

10. PHARMACOL. CATEGORY:
Antihypercholesterolemic, inhibitor of HMG-CoA reductase.

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
10 mg, 20 mg, 40 mg, and 80 mg

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X_Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
Atorvastatin Calcium
$(C_{33}H_{34}FN_2O_5)_2Ca$
CAS 134523-03-8

CAS 134523-00-5 (atorvastatin)

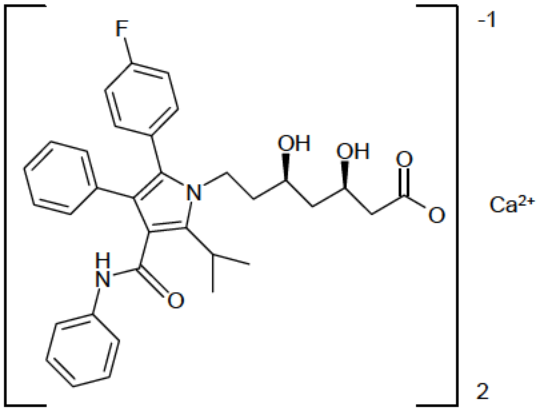
FW 2 x 557.7 + 40.0 = 1155.38

(b) (4)

1*H*-Pyrrole-heptanoic acid, 2-(4-fluorophenyl)-β,-δ-hydroxy-5-(methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-,calcium salt (2:1),[*R*-(*R**,*R**)]-

Reference ID: 3052070

Chemistry Review Data Sheet



17. RELATED/SUPPORTING DOCUMENTS

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
18082	II	Lek	Drug substance	1	Adequate	21-SEP-2011	Reviewed by G. Kang
(b) (4)	III		(b) (4)	4	N/A		USP test results are included.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	IV			4	N/A		
	III			4	N/A		
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		GRAS
(b) (4)	III			4	N/A		
DMF added in the amendment dated 11-MAR-2009.							
(b) (4) b) (4)	III		(b) (4)	4	N/A		Comply with 21 CFR 175.105, 170-199, 175-300.
	III			4	N/A		USP test results are included.
	III			4	N/A		Details on Page 108 (section XIII)
	III			4	N/A		Comply with 21 CFR 177.1520.
	III				N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.
	III			4	N/A		Comply with 21 CFR 177.1520.

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	acceptable	27-APR-2010	A. Inyard
Methods Validation	N/A		
Labeling	**acceptable**	10-JUN-2011	T. Vu
Bioequivalence	Dissolution: **acceptable*** BE: **acceptable**	 07-MAY-2010	X. Jiang L. Gong
EA	Waiver submitted		
Radiopharmaceutical	N/A		

* There is a "dissolution only" review (V:\firmsam\Lek\ltrs&rev\77575D0205.doc) and a "full ANDA" review (V:\firmsam\Lek\ltrs&rev\77575N0205.doc). As per the recommendation 3 on page the 12 of the "full ANDA" review, the firm has acknowledged the FDA-recommended method (900 ml of 0.05 M phosphate buffer pH 6.8 with paddles at 75 rpm) and specification [NLT (b) (4) (Q) in 15 minutes]. ------ Information taken from page 2 of 07-MAY-2010 Bio review (DARRTS).

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __X__ Yes ____ No If no, explain reason(s) below:

Reference ID: 3052070

The Chemistry Review for ANDA 077575

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

CMC section is **acceptable pending the note listed in II.C of this section.**
Labeling and Bio sections are acceptable.
EES is acceptable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

The reference listed drug for this application is Lipitor® Tablets 10 mg, 20, 30 mg and 40 mg by Pfizer. Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate limiting step in the biosynthesis of cholesterol.

Atorvastatin Calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin Calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Sandoz' Atorvastatin Calcium Tablets are manufactured using (b) (4) atorvastatin calcium whereas the Pfizer's Lipitor is manufactured using the crystalline atorvastatin calcium trihydrate.

Note: Drug substance meets the IR identification test under the modified <197K> conditions to the current USP monograph. The results have been confirmed by the Agency laboratories at St. Louis, Missouri. Therefore the Agency concludes that Sandoz' drug substance meet the USP monograph for the ID test per the API Sameness memorandum darrts dated Nov 30, 2011

There are references made to the USP pending monograph in the current review and earlier review cycles. However, referencing to pending monograph in the current and earlier review cycles has no impact on the satisfactory outcome for the drug substance per addendum darrts dated Nov 30, 2011.

Reference ID: 3052070

Atorvastatin Calcium Tablets contain atorvastatin calcium and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine.

The drug product is manufactured by (b) (4)

Stability batches were packaged in each strength of the smallest and largest size of each marketed container/closure system. The firm submitted three months accelerated and room temperature stability data. The firm has requested 24 months expiration date based on the three months accelerated stability data.

New bio-batch:
The firm has manufactured new bio-batch (30004016/AA3869) and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired. These new batches were manufactured using revised manufacturing processes (b) (4)

B. Description of How the Drug Product is Intended to be Used

Maximum Daily Dose is 80 mg/day as per Labeling insert information.

The drug substance: based on the ICH Guideline Q3A(R)
IT is 0.10% for any single unknown impurities (unspecified).
QT is 0.15% for any specified identified or specified unidentified impurity.

The drug product: based on the ICH Guideline Q3B(R)
IT is 0.20% for any single unknown impurities (unspecified).
QT is (b) (4) % for any specified identified or specified unidentified impurity.

C. Basis for Approvability or Not-Approval Recommendation

CMC is acceptable pending the following note*.
Bio and labeling sections are acceptable.
EES is acceptable.

**Note: ANDA approvability is pending Division review, other disciplines and/or EES. This CMC review may require an addendum based on recommendations made by other review disciplines.*

Chemistry Assessment

Reference ID: 3052070
82 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI/TS) IMMEDIATELY FOLLOWING THIS PAGE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
11/30/2011

LAXMA R NAGAVELLI
11/30/2011

LEIGH A SEARS
11/30/2011

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration

Center for Drug Evaluation and Research
Division of Pharmaceutical Analysis
1114 Market Street, Room 1002
St. Louis, Missouri 63101
Telephone (314) 539-3858
FAX (314) 539-2113

Date: November 10, 2011

To: Suhas Patankar, Ph.D., CDER/OGD

From: Jason D. Rodriguez, Ph.D., Chemist, OPS/OTR/ DPA
Anjanette P. Smith, Chemist, OPS/OTR/DPA

Through: B.J. Westenberger, Deputy Director, OPS/OTR/ DPA

Subject: IR Spectroscopic Study of Atorvastatin Calcium API

Background

The Office of Generic Drugs (OGD) requested the infrared (IR) spectroscopic analysis of test and USP Reference Standard samples for atorvastatin calcium active pharmaceutical ingredient (API) provided by four different applicants. Each test and reference sample was prepared for IR analysis using the dry United States Pharmacopeia (USP) <197K> method and the additional <197K> method with use of solvent. A summary of the methods is given in Appendix A. This report contains the IR spectroscopic identification results using these two preparatory routes.

Conclusion

The preparation method used for IR identification tests was shown to be critical in determining whether a particular test sample matched the USP reference standard. Test samples from all four applicants fail to meet the USP specification using the dry <197K> procedure. Test samples from three of the four applicants meet the USP specification using the solvent <197K> procedure. The Apotex test sample fails the USP specification due to an additional maximum at ~ (b) (4) cm^{-1}. This peak is likely due to residual (b) (4) present in the sample preparation. Similarity for all samples was evaluated using both the USP criteria (visual peak maxima comparison) and a computer-based correlation coefficient. The computer-based correlation coefficient indicated a strong match (>95%) for all samples using the solvent procedure.

Appendices

Appendix A: Preparation Details for Samples Analyzed by IR Spectroscopy
Appendix B: Brief Description of Spectroscopic Techniques and Methods used for Identification Tests
Appendix C: Results of Identification Tests

Reference ID: 3047027

Appendix A: Preparation Details for Samples Analyzed by IR Spectroscopy

Sample Number	Manufacturer (Applicant)	USP <197K> Method	USP<197K> with use of solvent
12-12A-000	Teva Pharmaceutical	Mixed 2 mg of USPRS with 300 mg KBr and pressed mixture into a pellet for analysis. Repeated procedure for test sample.	Dissolved equal portions of test sample and USPRS in equal volumes methanol, evaporated to dryness in similar containers under identical conditions. Mixed 2 mg of resulting residue with 300 mg KBr and pressed mixture into pellet for analysis.
12-12A-001	LEK D.D. (Sandoz)	Mixed 2 mg of USPRS with 300 mg KBr and pressed mixture into a pellet for analysis. Repeated procedure for test sample.	Dissolved equal portions of test sample and USPRS in equal volumes methanol, evaporated to dryness in similar containers under identical conditions. Mixed 2 mg of resulting residue with 300 mg KBr and pressed mixture into pellet for analysis.
12-12A-002	Matrix Pharmaceuticals Ltd. (Mylan)	Mixed 2 mg of USPRS with 300 mg KBr and pressed mixture into a pellet for analysis. Repeated procedure for test sample.	Applicant's method: Dissolved 5 mg test sample and USPRS in 1 mL methanol. Dried in petri dish in oven at 45°C for 15 min under vacuum (10-15 mm Hg). Mixed 2 mg of resulting residue with 300 mg KBr and pressed mixture into pellet for analysis.
11-90-548	Apotex	Mixed 2 mg of USPRS with 300 mg KBr and pressed mixture into a pellet for analysis. Repeated procedure for test sample.	Applicant's method: Dissolved 2 mg test sample and USPRS in 0.5mL of methanol then added 300 mg KBr. Dried entire mixture with nitrogen flow.and pressed mixture into pellet for analysis.

Important Abbreviations: USPRS (United States Pharmacopeia Reference Standard)
KBr (Potassium Bromide, a transparent material used for IR analysis)

Reference ID: 3047027

Appendix B: Brief Description of Spectroscopic Techniques and Methods used for Identification Tests

Sample Acquisition

Following the sample preparation techniques described in Appendix A, the samples were analyzed using the transmission sampling module on the Bruker Alpha-T FTIR spectrometer at DPA. Spectra were acquired under identical acquisition parameters: 4 cm^{-1} resolution, 16 scans (sample and background), and (b) (4) cm^{-1} spectral range. Spectra were reported using transmittance (%) vs. wavenumber (cm).

Identification Tests

Two types of identification tests were used to evaluate the spectra: 1) USP method and 2) Computer-based evaluation. Under the criteria used by the USP method, a test spectrum is assigned a "Pass" (i.e., is the same as the USP reference spectrum) if the spectrum contains maxima at the same wavelengths as that of a similar preparation of the corresponding USP reference standard. For the computer-based evaluation, the OPUS software from the Bruker instrument is programmed to compare the spectrum (using the "Quick Compare" functionality) of the USP reference sample to the test sample by calculating the correlation coefficient. This value ranges between -1 to +1, but the program utilizes only the positive range and the negative values are reported as 0. Under this convention, the working range of the correlation coefficient is between 0 (poorest match) and 1 (perfect match). The OPUS program reports these values as percentages, so the range is essentially 0% to 100% and the value may be thought of as a hit quality index (HQI)[1]. Since broad baselines in the spectra may artificially result in high correlations,[2] even for obviously different spectra, we added first derivative preprocessing to reduce baseline effects. The threshold that must be met for a "Pass" is 95%.

[1.] Rodriguez, J. D.; Westenberger, B. J.; Buhse, L. F.; Kauffman, J. F. Quantitative Evaluation of the Sensitivity of Library-Based Raman Spectral Correlation Methods. *Anal. Chem.***2011**, *83*, 4061.

[2.] Kauffman, J. F.; Rodriguez, J. D.; Buhse, L. F. Spectral Preprocessing for Raman Searches. *Am. Pharm. Review*.**2011**, *14*, 34.

Reference ID: 3047027

Appendix C: Results of Identification Tests

Sample Number	Manufacturer (Applicant)	USP RS Lot #	Test Sample Lot #	<197K> Preparation USP Criteria ID Test	<197K> Preparation Quick Compare Test (HQI)	USP<197K> with use of solvent USP Criteria ID Test	USP<197K> with use of solvent Quick Compare Test (HQI)
12-12A-000	Teva Pharmaceutical	G0J276	7854ST01-786608810	FAIL	FAIL 65.37 %	PASS	PASS 99.46%
		G0J276	7866-24111	FAIL	FAIL 65.14%	PASS	PASS 98.12%
		G0J276	7866-24211	FAIL	FAIL 63.37%	PASS	PASS 99.15%
		G0J276	7866-24311	FAIL	FAIL 64.82%	PASS	PASS 99.90%
12-12A-001	LEK D.D. (Sandoz)	G0J276	B077055	FAIL	FAIL 62.95%	PASS	PASS 99.59%
12-12A-002	Matrix Pharmaceuticals Ltd. (Mylan)	F0I169	QCD-3/ASC/WS001/10	FAIL	FAIL 61.69%	PASS	PASS 99.74%
11-90-548	Apotex	G0J276	JX9789[a]	FAIL	FAIL 72.15%	Fail[b]	PASS 98.84% 97.83%

Note: USP Test Pass/Fail Criteria: Based on visual inspection of overlay of USP RS and test spectrum to meet criteria outlined in Appendix B. Quick Compare Test Criteria: Must be above the 95% similarity threshold. [a] Apotex lot JX9789 was run twice on different days. [b] Due to an extra peak in the test spectrum (for both trials) at ~ (b) (4) cm^{-1} that is likely due to residual (b) (4) present in the sample.

Reference ID: 3047027

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES F ALLGIRE
11/18/2011

ANDA 077575

Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

Sandoz Inc.

(Ownership has been transferred to Sandoz Inc. from Lek Pharmaceuticals d.d.)

Gil-Jong Kang
Office of Generic Drugs
Division of Chemistry III
Team 31

Table of Contents

Table of Contents **2**

Chemistry Review Data Sheet **3**

The Executive Summary **8**

I. Recommendations 8

A. Recommendation and Conclusion on Approvability 8

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable 8

II. Summary of Chemistry Assessments 8

A. Description of the Drug Product(s) and Drug Substance(s) 8

B. Description of How the Drug Product is Intended to be Used 9

C. Basis for Approvability or Not-Approval Recommendation 9

Chemistry Assessment (Part I) **10**

Chemistry Assessment (Part II) **45**

Chemistry Review Data Sheet

1. ANDA # 077575

2. REVIEW # 5_final for Approval

3. REVIEW DATE: 27-APR-2011, 27-JUN-2011, revised 02-OCT-2011

4. REVIEWER: Gil-Jong Kang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	11-FEB-2005
Acceptable for filing	18-FEB-2005
Amendment (Telephone)	01-APR-2005
Correspondence (Change of US agent)	17-JUN-2005
Deficiency letter based on Review #1	31-AUG-2005
Pharm/Tox consult result (tromethamine)	03-OCT-2005
Minor amendment & Change of US agent	12-OCT-2005
Deficiency letter based on Review #2	13-MAR-2006
Minor amendment	02-OCT-2006
Deficiency letter based on Review #3	25-APR-2007
Minor amendment	26-SEP-2007
Correspondence (Transfer of ownership from Lek to Sandoz)	17-MAY-2010
Pharm/Tox consult review	26-AUG-2010 & 01-SEP-2010
Deficiency letter based on Review #4	27-SEP-2010

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Major amendment (revised manufacturing process and new bio batch)	11-MAR-2009
Minor amendment (Response)	24-MAR-2011
Pharm/Tox consult review	04-MAY-2011
Pharm/Tox consult review	25-MAY-2011

Reference ID: 3019557

Chemistry Review Data Sheet

Telephone amendment/ Packaging changes	14-JUN-2011
Telephone amendment/ Packaging changes	22-JUN-2011
Telephone amendment/ Packaging changes	13-JUL-2011
Telephone amendment (Impurity)	30-AUG-2011

7. NAME & ADDRESS OF APPLICANT:

Name: Sandoz Inc.

Address: 506 Carnegie Center
Suite 400
Princeton, NJ 08540

Representative: Bernadette Attinger

Telephone: (609) 627-8865
Fax: (609) 395-2792

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Atorvastatin Calcium Tablets

9. LEGAL BASIS FOR SUBMISSION:

Reference listed drug: Lipitor® Tablets
Pfizer
Application Number: N020702
Strength: 10 mg, 20 mg, 40 mg and 80 mg

Patent Certification:

-Paragraph III Certification (p.13)

Sandoz certifies that, U.S. patent No. 4,681,893 will expire on 24-MAR-2010, and U.S. patent No. 5,273,995 will expire on 28-JUN-2011. Sandoz certifies that approval of the Lek product is sought to be effective upon expiration of both patents stated above.
Sandoz included a Paragraph III certification for US Patent No. RE40667 in patent amendment dated 15-JUN-2010

-Paragraph IV Certification (p.14)

Lek certifies that to the best of its knowledge, U.S. patent Nos. 5,686,104; 5,969,156 and 6,126,971 which will expire on 11-MAY-2015, 08-JAN-2017 and 19-JUL, 2013, respectively are invalid or will not be infringed by the manufacture, use or sale of Lek product.

Lek will comply with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner, or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95(c) with respect to the contents of the notice.

Reference ID: 3019557

Exclusivity statement:

The applicant does not seeking approval until after the date of expiry of the U. S. Patents No. 5,273,995 on 28-JUN-2011.

Exclusivity	Expiration
D-77	22-APR-2005
M-36	30-JUL-2007
I-434	30-JUL-2007
I-350	18-OCT-2005
PED	18-APR-2006

10. PHARMACOL. CATEGORY:

Antihypercholesterolemic, inhibitor of HMG-CoA reductase.

11. DOSAGE FORM:

Tablets

12. STRENGTH/POTENCY:

10 mg, 20 mg, 40 mg, and 80 mg

13. ROUTE OF ADMINISTRATION:

Oral

14. Rx/OTC DISPENSED: _X_Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Atorvastatin Calcium

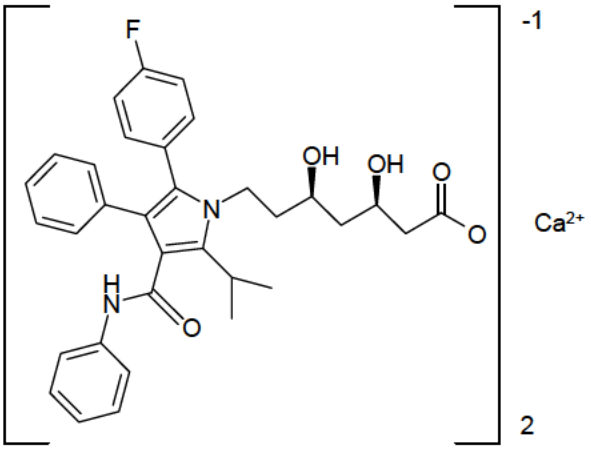
$(C_{33}H_{34}FN_2O_5)_2Ca$
CAS 134523-03-8
CAS 134523-00-5 (atorvastatin)

FW 2 x 557.7 + 40.0 = 1155.38

(b) (4)

1*H*-Pyrrole-heptanoic acid, 2-(4-fluorophenyl)-β,-δ-hydroxy-5-(methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-,calcium salt (2:1),[*R*-(*R**,*R**)]-

Reference ID: 3019557



17. RELATED/SUPPORTING DOCUMENTS

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
18082	II	Lek	Drug substance	1	Adequate	21-SEP-2011	Reviewed by G. Kang
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		USP test results are included.
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 177.1520.
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 177.1520.
(b) (4)	IV	(b) (4)	(b) (4) t	4	N/A		
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 177.1520.
(b) (4)	III	(b) (4)	(b) (4) t	4	N/A		GRAS
(b) (4)	III	(b) (4)	(b) (4)	4	N/A		
DMF added in the amendment dated 11-MAR-2009.							
(b) (4)	III	(b) (4) (b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 175.105, 170-199, 175-300.
(b) (4)	III			4	N/A		USP test results are included.
(b) (4)	III			4	N/A		Details on Page 108 (section XIII)
(b) (4)	III			4	N/A		Comply with 21 CFR 177.1520.
(b) (4)	III				N/A		Comply with 21 CFR 177.1520.
(b) (4)	III			4	N/A		Comply with 21 CFR 177.1520.
(b) (4)	III			4	N/A		Comply with 21 CFR 177.1520.

Chemistry Review Data Sheet

(b) (4)	III	(b) (4)	(b) (4)	4	N/A		Comply with 21 CFR 177.1520.

* (b) (4)

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	acceptable	27-APR-2010	A. Inyard
Methods Validation	N/A		
Labeling	**acceptable**	10-JUN-2011	T. Vu
Bioequivalence	Dissolution: **acceptable*** BE: **acceptable**	07-MAY-2010	X. Jiang L. Gong
EA	Waiver submitted		
Radiopharmaceutical	N/A		

* There is a "dissolution only" review (V:\firmsam\Lek\ltrs&rev\77575D0205.doc) and a "full ANDA" review (V:\firmsam\Lek\ltrs&rev\77575N0205.doc). As per the recommendation 3 on page the 12 of the "full ANDA" review, the firm has acknowledged the FDA-recommended method (900 ml of 0.05 M phosphate buffer pH 6.8 with paddles at 75 rpm) and specification [NLT (b) (4) (Q) in 15 minutes]. ------ Information taken from page 2 of 07-MAY-2010 Bio review (DARRTS).

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. __X__ Yes ____ No If no, explain reason(s) below:

Reference ID: 3019557

The Chemistry Review for ANDA 077575

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

CMC section is **acceptable pending the note listed in II.C of this section.**
Labeling and Bio sections are acceptable.
EES is acceptable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

The reference listed drug for this application is Lipitor® Tablets 10 mg, 20, 30 mg and 40 mg by Pfizer. Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate limiting step in the biosynthesis of cholesterol.

Leks' Atorvastatin Calcium Tablets contain (b) (4) atorvastatin calcium and the RLD contain **crystalline** atorvastatin calcium **trihydrate**.

Atorvastatin Calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin Calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Atorvastatin Calcium Tablets contain atorvastatin calcium and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine.

The drug product is manufactured by (b) (4)

Reference ID: 3019557

Stability batches were packaged in each strength of the smallest and largest size of each marketed container/closure system. The firm submitted three months accelerated and room temperature stability data. The firm has requested 24 months expiration date based on the three months accelerated stability data.

(Note)
The firm has manufactured new bio-batch (30004016/AA3869) and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired. These new batches were manufactured using revised manufacturing processes (b) (4)).

B. Description of How the Drug Product is Intended to be Used

Maximum Daily Dose is 80 mg/day as per Labeling insert information.

The drug substance: based on the ICH Guideline Q3A(R)
IT is 0.10% for any single unknown impurities (unspecified).
QT is 0.15% for any specified identified or specified unidentified impurity.

The drug product: based on the ICH Guideline Q3B(R)
IT is 0.20% for any single unknown impurities (unspecified).
QT is (b) (4) % for any specified identified or specified unidentified impurity.

C. Basis for Approvability or Not-Approval Recommendation

CMC is acceptable pending the following note*.
Labeling section is acceptable.
Bio section is acceptable.
EES is acceptable.

**Note: The CMC review is currently acceptable per the review team recommendations. However, the drug substance description in the label is not in compliance with the official or pending monograph as it fails to include the solid state form as required by USP and declared in the application. ANDA approvability is pending Division review, other disciplines and/or EES. This CMC review may require an addendum based on recommendations made by other review disciplines. Please refer to the attached email (end of the review) from Bob West to address the issue of drug substance description prior to approval.*

Reference ID: 3019557
82 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI/TS) IMMEDIATELY FOLLOWING THIS PAGE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
10/03/2011

LAXMA R NAGAVELLI
10/03/2011
The drug substance description in the label needs to be resolved.

LEIGH A SEARS
10/06/2011

ANDA 077575

Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

Sandoz Inc.

(Ownership has been transferred to Sandoz Inc. from Lek Pharmaceuticals d.d.)

Gil-Jong Kang
Office of Generic Drugs
Division of Chemistry III
Team 4

Table of Contents

Table of Contents **2**

Chemistry Review Data Sheet **3**

The Executive Summary **8**

I. Recommendations 8

A. Recommendation and Conclusion on Approvability 8

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable 8

II. Summary of Chemistry Assessments 8

A. Description of the Drug Product(s) and Drug Substance(s) 8

B. Description of How the Drug Product is Intended to be Used 9

C. Basis for Approvability or Not-Approval Recommendation 9

Chemistry Assessment **10**

Chemistry Review Data Sheet

1. ANDA # 077575

2. REVIEW # 4

3. REVIEW DATE: 20-JUL-2010, revised 15-SEP-2010 (due to consult result)

4. REVIEWER: Gil-Jong Kang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	11-FEB-2005
Acceptable for filing	18-FEB-2005
Amendment (Telephone)	01-APR-2005
Correspondence (Change of US agent)	17-JUN-2005
Deficiency letter based on Review #1	31-AUG-2005
Pharm/Tox consult result (tromethamine)	03-OCT-2005
Minor amendment & Change of US agent	12-OCT-2005
Deficiency letter based on Review #2	13-MAR-2006
Minor amendment	02-OCT-2006
Deficiency letter based on Review #3	25-APR-2007

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Minor amendment	26-SEP-2007
Transfer of ownership	17-MAY-2010

7. NAME & ADDRESS OF APPLICANT:

Name: Sandoz Inc.

Chemistry Review Data Sheet

Address: 506 Carnegie Center
Suite 400
Princeton, NJ 08540

Representative: William Kwok

Telephone: (609) 627-8854
Fax: (609) 395-2792

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Atorvastatin Calcium Tablets

9. LEGAL BASIS FOR SUBMISSION:

Reference listed drug: Lipitor® Tablets
Pfizer
Application Number: N020702
Strength: 10 mg, 20 mg, 40 mg and 80 mg

Patent Certification: p.10

-Paragraph III Certification (p.13)

Lek certifies that, U.S. patent No. 4,681,893 will expire on 24-MAR-2010, and U.S. patent No. 5,273,995 will expire on 28-JUN-2011. Lek certifies that approval of the Lek product is sought to be effective upon expiration of both patents stated above.

-Paragraph IV Certification (p.14)

Lek certifies that to the best of its knowledge, U.S. patent Nos. 5,686,104; 5,969,156 and 6,126,971 which will expire on 11-MAY-2015, 08-JAN-2017 and 19-JUL, 2013, respectively are invalid or will not be infringed by the manufacture, use or sale of Lek product.

Lek will comply with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner, or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95(c) with respect to the contents of the notice.

Exclusivity statement: p.16

The applicant does not seeking approval until after the date of expiry of the U. S. Patents No. 5,273,995 on 28-JUN-2011.

Chemistry Review Data Sheet

Exclusivity	Expiration
D-77	22-APR-2005
M-36	30-JUL-2007
I-434	30-JUL-2007
I-350	18-OCT-2005
PED	18-APR-2006

10. PHARMACOL. CATEGORY:
Antihypercholesterolemic, inhibitor of HMG-CoA reductase.

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
10 mg, 20 mg, 40 mg, and 80 mg

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X_Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

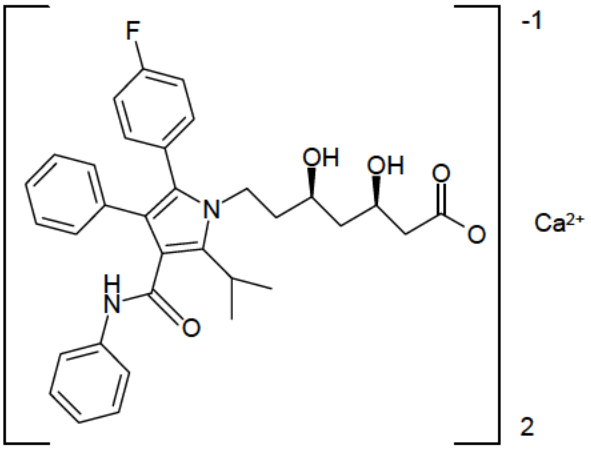
16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Atorvastatin Calcium

$(C_{33}H_{34}FN_2O_5)_2Ca$
CAS 134523-03-8
CAS 134523-00-5 (atorvastatin)

FW 2 x 557.7 + 40.0 = 1155.38
(b) (4)

1*H*-Pyrrole-heptanoic acid, 2-(4-fluorophenyl)-β,-δ-hydroxy-5-(methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-,calcium salt (2:1),[*R*-(*R**,*R**)]-



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
18082	II	Lek	Drug substance	1	Inadequate	15-SEP-2010	Reviewed by G. Kang
(b) (4)	III	(b) (4)	(b) (4)	4			USP test results are included.
(b) (4)	III			4			Comply with 21 CFR 177.1520.
(b) (4)	III			4			
(b) (4)	IV			4			
(b) (4)	III			4			
(b) (4)	III			4			
(b) (4)	III			4			Comply with 21 CFR 177.105, 177.300.
(b) (4)	III			4			
(b) (4)	III			4			

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	acceptable	27-APR-2010	
Methods Validation	N/A		
Labeling	acceptable	10-JUL-2006	B. Weitzman
Bioequivalence	Dissolution: **acceptable*** BE: **acceptable**	07-MAY-2010	X. Jiang L. Gong
EA	Waiver submitted		
Radiopharmaceutical	N/A		

* There is a "dissolution only" review (V:\firmsam\Lek\ltrs&rev\77575D0205.doc) and a "full ANDA" review (V:\firmsam\Lek\ltrs&rev\77575N0205.doc). As per the recommendation 3 on page the 12 of the "full ANDA" review, the firm has acknowledged the FDA-recommended method (900 ml of 0.05 M phosphate buffer pH 6.8 with paddles at 75 rpm) and specification [NLT (b) (4) (Q) in 15 minutes]. ------ Information taken from page 2 of 07-MAY-2010 Bio review (Darrts).

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ____ Yes __X__ No If no, explain reason(s) below: MINOR

The Chemistry Review for ANDA 077575

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is not approvable.
CMC section is deficient (Minor).
Bio and labeling sections are acceptable.
EES is acceptable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

The reference listed drug for this application is Lipitor® Tablets 10 mg, 20, 30 mg and 40 mg by Pfizer. Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate limiting step in the biosynthesis of cholesterol.

Leks' Atorvastatin Calcium Tablets contain (b) (4) atorvastatin calcium and the RLD contain crystalline atorvastatin calcium trihydrate.

Atorvastatin Calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin Calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Atorvastatin Calcium Tablets contain atorvastatin calcium and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine.

The drug product is manufactured by (b) (4) .

Stability batches were packaged in each strength of the smallest and largest size of each marketed container/closure system. The firm submitted three months accelerated and room temperature stability data. The firm has requested 24 months expiration date based on the three months accelerated stability data.

B. Description of How the Drug Product is Intended to be Used

Maximum Daily Dose is 80 mg/day as per Labeling insert information.

The drug substance: based on the ICH Guideline Q3A(R)

IT is 0.10% for any single unknown impurities (unspecified).
QT is 0.15% for any specified identified or specified unidentified impurity.

The drug product: based on the ICH Guideline Q3B(R)

IT is 0.20% for any single unknown impurities (unspecified).
QT is (b) (4)% for any specified identified or specified unidentified impurity.

C. Basis for Approvability or Not-Approval Recommendation

The application is not approvable.
CMC section is deficient.
Bio and labeling sections are acceptable.
EES is acceptable.

30 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI/TS) IMMEDIATELY FOLLOWING THIS PAGE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
09/23/2010

SARAH K NGUYEN
09/23/2010
revision

SHING HOU H LIU
09/27/2010

ANDA 77-575

Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

Lek Pharmaceuticals d.d.

Gil-Jong Kang
Chemistry III

Table of Contents

Table of Contents **2**

Chemistry Review Data Sheet **3**

The Executive Summary **8**

I. Recommendations 8

A. Recommendation and Conclusion on Approvability 8

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable 8

II. Summary of Chemistry Assessments 8

A. Description of the Drug Product(s) and Drug Substance(s) 8

B. Description of How the Drug Product is Intended to be Used 9

C. Basis for Approvability or Not-Approval Recommendation 9

Chemistry Assessment **10**

Chemistry Review Data Sheet

1. ANDA 77-575

2. REVIEW # 3

3. REVIEW DATE: 11-APR-2007

4. REVIEWER: Gil-Jong Kang

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original	11-FEB-2005
Acceptable for filing	18-FEB-2005
Amendment (Telephone)	01-APR-2005
Correspondence (Change of US agent)	17-JUN-2005
Deficiency letter based on Review #1	31-AUG-2005
Pharm/Tox consult result (tromethamine)	03-OCT-2005
Minor amendment & Change of US agent	12-OCT-2005
Deficiency letter based on Review #2	13-MAR-2006

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Minor amendment	02-OCT-2006

7. NAME & ADDRESS OF APPLICANT:

Name: Lek Pharmaceuticals d.d.

Address: Verovskova 57
1526 Ljubljana
Slovenia

Representative: Carmelle Lucas
Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540
Telephone: (609) 627-8854
Fax: (609) 395-2792

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Atorvastatin Calcium Tablets

9. LEGAL BASIS FOR SUBMISSION:

Reference listed drug: Lipitor® Tablets
Pfizer
Application Number: N020702
Strength: 10 mg, 20 mg, 40 mg and 80 mg

Patent Certification: p.10

-Paragraph III Certification (p.13)

Lek certifies that, U.S. patent No. 4,681,893 will expire on 24-MAR-2010, and U.S. patent No. 5,273,995 will expire on 28-JUN-2011. Lek certifies that approval of the Lek product is sought to be effective upon expiration of both patents stated above.

-Paragraph IV Certification (p.14)

Lek certifies that to the best of its knowledge, U.S. patent Nos. 5,686,104; 5,969,156 and 6,126,971 which will expire on 11-MAY-2015, 08-JAN-2017 and 19-JUL, 2013, respectively are invalid or will not be infringed by the manufacture, use or sale of Lek product.

Lek will comply with the requirements under 21 CFR 314.95(a) with respect to providing a notice to each owner, or their representatives and to the holder of the approved drug application for the listed drug, and with the requirements under 21 CFR 314.95(c) with respect to the contents of the notice.

Exclusivity statement: p.16

The applicant does not seeking approval until after the date of expiry of the U. S. Patents No. 5,273,995 on 28-JUN-2011.

Exclusivity	Expiration
D-77	22-APR-2005
M-36	30-JUL-2007
I-434	30-JUL-2007
I-350	18-OCT-2005
PED	18-APR-2006

10. PHARMACOL. CATEGORY:
Antihypercholesterolemic, inhibitor of HMG-CoA reductase.

11. DOSAGE FORM:
Tablets

12. STRENGTH/POTENCY:
10 mg, 20 mg, 40 mg and 80 mg

13. ROUTE OF ADMINISTRATION:
Oral

14. Rx/OTC DISPENSED: _X_ Rx ___ OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

__X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

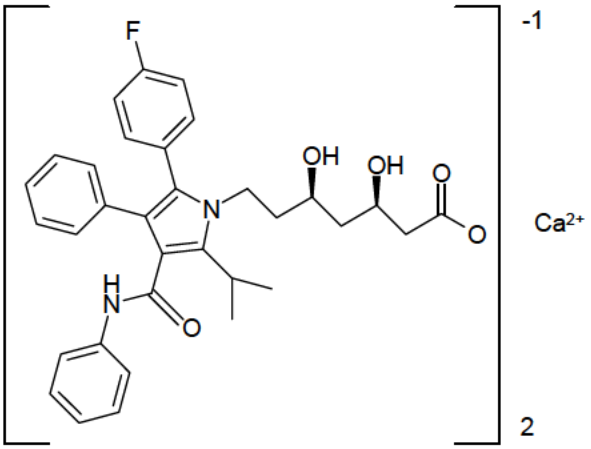
Atorvastatin Calcium

$(C_{33}H_{34}FN_2O_5)_2Ca$
CAS 134523-03-8
CAS 134523-00-5 (atorvastatin)

FW 2 x 557.7 + 40.0 = 1155.38

(b) (4)

1*H*-Pyrrole-heptanoic acid, 2-(4-fluorophenyl)-β,-δ-hydroxy-5-(methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-,calcium salt (2:1),[*R*-(*R**,*R**)]-



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
18082	II	Lek	Drug substance	1	Inadequate	06-APR-2007	By G. Kang
(b) (4)	III	(b) (4)		4			USP test results are included.
(b) (4)	III			4			Comply with 21 CFR 177.1520.
(b) (4)	III			4			
(b) (4)	IV			4			
(b) (4)	III			4			
(b) (4)	III			4			
(b) (4)	III			4			Comply with 21 CFR 177.105, 177.300.
(b) (4)	III			4			
(b) (4)	III			4			

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Microbiology	N/A		
EES	acceptable	19-DEC-2006	
Methods Validation	N/A		
Labeling	acceptable	10-AUG-2006	B. Weitzman
Bioequivalence	Dissolution: **acceptable** BE: **deficient**	15-NOV-2005 05-MAR-2007	X. Jiang Y. Huang
EA	Waiver submitted		
Radiopharmaceutical	N/A		

19. ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt. ____ Yes __X__ No If no, explain reason(s) below: MINOR

The Chemistry Review for ANDA 77-575

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

The application is not approvable.
CMC and Bio sections are deficient.
Labeling and EES are acceptable.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

The reference listed drug for this application is Lipitor® Tablets 10 mg, 20, 30 mg and 40 mg by Pfizer. Atorvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. The enzyme catalyzes the conversion of HMG-CoA to mevalonate, which is an early and rate limiting step in the biosynthesis of cholesterol.

Leks' Atorvastatin Calcium Tablets contain (b) (4) atorvastatin calcium and the RLD contain crystalline atorvastatin calcium trihydrate.

Atorvastatin Calcium is a white to off-white powder that is insoluble in aqueous solutions of pH 4 and below. Atorvastatin Calcium is very slightly soluble in distilled water, pH 7.4 phosphate buffer, and acetonitrile, slightly soluble in ethanol, and freely soluble in methanol.

Atorvastatin Calcium Tablets contain atorvastatin calcium and the following inactive ingredients: Carboxymethylcellulose Sodium, Ferric Oxide Yellow, Glycerin, Magnesium Stearate, Pregelatinized Starch, Silicified Microcrystalline Cellulose, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Talc, Tromethamine.

The drug product is manufactured by (b) (4) .

Stability batches were packaged in each strength of the smallest and largest size of each marketed container/closure system. The firm submitted three months accelerated and room temperature stability data. The firm has requested 24 months expiration date based on the three months accelerated stability data.

B. Description of How the Drug Product is Intended to be Used

Maximum Daily Dose is 80 mg/day as per Labeling insert information.

The drug substance: based on the ICH Guideline Q3A(R)

IT is 0.10% for any single unknown impurities (unspecified).
QT is 0.15% for any specified identified or specified unidentified impurity.

The drug product: based on the ICH Guideline Q3B(R)

IT is 0.20% for any single unknown impurities (unspecified).
QT is (b) (4) % for any specified identified or specified unidentified impurity.

C. Basis for Approvability or Not-Approval Recommendation

CMC responses are not acceptable. DMF is still inadequate.
Bio is deficient.
Labeling and EES are acceptable.
Deficiencies are classified as MINOR.

21 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI/TS) IMMEDIATELY FOLLOWING THIS PAGE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Gil Jong Kang
4/24/2007 04:03:58 PM
CHEMIST

Leigh Matheny
4/25/2007 12:41:19 PM
CSO

Devinder Gill
4/25/2007 01:13:26 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

BIOEQUIVALENCE REVIEWS

DIVISION OF BIOEQUIVALENCE REVIEW OF AN AMENDMENT

ANDA No.	077575		
Drug Product Name	Atorvastatin Calcium Tablets		
Strength(s)	10 mg, 20 mg, 40 mg and 80 mg		
Applicant Name*	Sandoz Inc.		
Address	506 Carnegie Center, Suite 400 Princeton, NJ 08540		
Applicant's Point of Contact	William Kwok Associate Director, Regulatory Affairs		
Contact's Telephone Number	609-627-8854		
Contact's Fax Number	609-395-2792		
Original Submission Date(s)	February 18, 2005		
Submission Date(s) of Amendment(s) Under Review	March 02, 2010 (current amendment)		
Reviewer	Li Gong, Ph.D.		
Study Number (s)	80018	AA05474	AA05473
Study Type (s)	Fasting	Fasting (failed study)	Fed
Strength (s)	80 mg	80 mg	80 mg
Clinical Site	Anapharm		
Clinical Site Address	4101 Yonge Street, Suite 600 P.O. Box 222 Toronto (Ontario) CANADA M2P 1N6		
Analytical Site	(b) (4)		
Analytical Site Address			
OVERALL REVIEW RESULT	**ADEQUATE**		
DSI REPORT RESULT	**ADEQUATE**		
Bioequivalence Study Tracking/supporting Document #	**Study / Test Type**	**Strength**	**Review Result**
21	**Dissolution**	**10, 20, 40 and 80 mg**	**Adequate**
21	**Fasting**	**80 mg**	**Adequate**

Review of an Amendment

I. Executive Summary

This ANDA references Pfizer's Lipitor® Tablets from NDA 20702.

According to the last review on this ANDA the fasting bioequivalence (BE) study was incomplete because of 2 deficiencies [see DARRTS for ANDA 077575 GONG, LI 12/06/2009 N/A 12/06/2009 REV-BIOEQ-01(General Review) Original-1 Archive]. Those 2 deficiencies were (i) the firm did not submit analytical raw data for all the study subjects and (ii) the firm was requested to conduct additional dissolution testing on the lower strength of 40 mg of the test product. In this amendment the firm is responding to those 2 deficiencies. The firm's responses are acceptable. The fasting BE study is now acceptable (**adequate).** Earlier the fed BE study was found acceptable (V:\firmsam\Lek\ltrs&rev\77575N0205.doc).
[For historical details see background section on page 3].

There is a "dissolution only" review (V:\firmsam\Lek\ltrs&rev\77575D0205.doc) and a "full ANDA" review (V:\firmsam\Lek\ltrs&rev\77575N0205.doc). As per the recommendation 3 on page the 12 of the "full ANDA" review, the firm has acknowledged the FDA-recommended method (900 ml of 0.05 M phosphate buffer pH 6.8 with paddles at 75 rpm) and specification [NLT (b) (4) (Q) in 15 minutes]. The dissolution data submitted in this amendment confirms that. Thus, the firm's *in vitro* dissolution testing using the FDA-recommended method and specification is acceptable (**adequate)**.

The DBE grants the waiver requests for *in vivo* BE study requirements for the following strengths: (i) 10 mg, (ii) 20 mg, and (iii) 40 mg of the test product, based on criteria set forth in 21 CFR § 320.22 (d) (2).

No Division of Scientific Investigations (DSI) inspection is pending or necessary. The clinical site was last inspected for the ANDA 90-486 (routine) on 1/23/2009 with the result of VAI and the analytical site was last inspected for the (b) (4) (routine) on (b) (4) with the result of NAI.

With this amendment the ANDA 077575 is now complete (**adequate).**

II. Table of Contents

I. Executive Summary 2
II. Table of Contents 3
III. Submission Summary 3
A. Drug Product Information, PK/PD Information, and Relevant DBE History 4
B. Contents of Submission 4
C. Review of Amendment Submissions 4
D. Deficiency Comments 8
E. Recommendations 8
F. Outcome Page 11

III. Submission Summary

Background

I. The firm submitted its original application on February 18, 2005. The firm conducted the fasting and fed BE studies on its test product, Atorvastatin Calcium Tablets, 80 mg, comparing it to the corresponding reference product, Lipitor® (Atorvastatin Calcium) Tablet, 80 mg, and also submitted waiver requests of *in vivo* BE requirements for the lower strengths of the test product, 10 mg, 20 mg and 40 mg. The fed BE study was found acceptable, however, the fasting BE study was found not acceptable because the 90% of confidence interval (CI) of log transformed Cmax of Atorvastatin in the fasting study was outside the acceptable range of [80.00-125.00%] (firm's LnCmax was 98.5-126.72%). Also, the biowaiver requests for Atorvastatin Calcium Tablets, 10 mg, 20 mg and 40 mg, respectively were denied due to unacceptable fasting BE study (V:\firmsam\Lek\ltrs&rev\77575N0205.doc).

II. The firm was advised to address the deficiencies related to the statistical analyses of the failed fasting BE study [see DARRTS for ANDA 077575 of HUANG, YIH CHAIN 03/05/2007 REV-BIOEQ-01 (General Review) Archive].

III. On April 4, 2007, the firm submitted an amendment in response to the DBE's deficiency letter dated 03/17/2007 and an audit report (prepared by (b) (4)) on two BE studies (AA05474 and AA05473) conducted and analyzed at (b) (4) ((b) (4) The audit report was accepted by the DBE whereas the amendment was found incomplete since the firm's response on the statistical analyses of the failed fasting study data was incomplete [see DARRTS for ANDA 077575 of PRADHAN, SIKTA 12/20/2007: REV-BIOEQ-01 (General Review) Archive].

IV. The firm has manufactured new test batches [Batch#s: 001179803I, 001196903I, 001198003I and 30004016/AA3869 (new biobatch)] and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired. These new batches were manufactured using revised manufacturing processes.

V. On March 11, 2009, the firm submitted the data of a new fasting BE study using the new batches of the test and reference products of Atorvastatin Calcium Tablets. In addition, the firm also submitted comparative dissolution data of the new batches of the test (four new batches including the new biobatch) and reference (only one batch which was used in the new fasting BE study) products using the FDA-recommended method. However, the firm's new fasting BE study was found inadequate because the firm did not submit analytical raw data for all the study subjects. Also, the firm was asked to conduct additional dissolution testing on the lower strength of 40 mg of the test product.

VI. On March 02, 2010, the firm submitted the current amendment in response to the deficiency letter dated December 11, 2009. The firm addressed the deficiencies identified by the DBE.

A. Drug Product Information, PK/PD Information, and Relevant DBE History

See DARRTS for ANDA 077575 of GONG, LI 12/06/2009 - REV-BIOEUQ-01 (General Review) Archive.

B. Contents of Submission

Study Types	Yes/No?	How many?
Single-dose fasting	No	
Single-dose fed	No	
Steady-state	No	
In vitro dissolution	No	
Waiver requests	No	
BCS Waivers	No	
Vasoconstrictor Studies	No	
Clinical Endpoints	No	
Failed Studies	No	
Amendments	Yes	1

C. Review of Amendment Submissions

Deficiency #1: *For your fasting bioequivalence (BE) study (Study No. 80018), you did not submit complete raw numerical data of all study sample assay and reassay runs. The raw data should include the peak area/height for the drug, peak area/height for the internal standard, ratio of the peak area/height for the drug to the peak area/height for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each assayed and reassayed sample, calibration standard samples, and quality control samples.*

Firm's Response to Deficiency #1:

"Sandoz acknowledges the agency's comment, the complete raw data of all study sample assay and reassay runs for Study No. 80018 and the summary of sample reassay coding are enclosed on the CD (Attachment-1)"

Reviewer's Comments on Firm's Response to Deficiency #1:

- The reviewer checked and verified that the firm submitted all the raw numerical data for all assay and reassay runs for the study subjects in the current amendment.

- The sample that was reanalyzed under the reason of "Sample reanalyzed to obtain confirming value (Code G)" is deemed PK repeat by the reviewer as shown in the following table:

Subject	Period	Time	Original Assay Conc	Repeat Assay Conc	Final Reported Conc
#75	2	1.0 h	43433.58 pg/mL	54614.78 pg/mL	54614.78 pg/mL

  The reviewer re-ran the SAS program using the original value to assess any potential effect on the outcome of the fasting study and found that 90% CI of the PK parameters still met the BE criteria of 80-125%.

- **Thus, the firm's response to the deficiency #1 is acceptable.**

Deficiency #2: *Your dissolution testing data based on the FDA-recommended dissolution method are adequate only for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. However, for the 40 mg (Lot # A01198003I) strength of the test product, it was observed that one tablet had unusually low dissolution at 5, 10 and 15 min which contributed to very high coefficient of variation (CV%) for the mean dissolution values at these sampling time points. To confirm the reproducibility and accuracy of your dissolution data from the 40 mg strength of the test product, please repeat the dissolution testing using the following FDA-recommended method for the 40 mg strength only. The DBE will set the specification for all strengths of the test product after evaluating the additional dissolution data.*

The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate Buffer, pH 6.8, at 37 ± 0.5 ^{0}C, using USP apparatus II at 75 rpm.

Firm's Response to Deficiency #2:

"We acknowledge the agency's comment to confirm the reproducibility and accuracy of dissolution data for 40 mg strength, Sandoz is submitting the repeated dissolution testing data using the FDA recommended method. The dissolution testing data is enclosed on the CD (Attachment-2).

From the firm's Attachment-2:

3. Dissolution results

3.1. The 1st analysis

Table 1: Percent dissolved of atorvastatin from Atorvastatin calcium film-coated tablet 40 mg tablets, Lot no. A01198003I in 900 mL phosphate buffer pH 6.8 at 37°C, Apparatus 2, USP, 75 rpm, Q is (b) (4)% in 15 minutes

Tablet no.	Percent dissolved in minutes				
	5	10	15	30	45
1	(b) (4)				
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
Mean	26.4	83.0	92.8	97.3	98.7
Range	(b) (4)				
RSD	43.6	23.5	7.4	2.4	1.4

3.2. The 2nd analysis

Table 2: Percent dissolved of atorvastatin from Atorvastatin calcium film-coated tablet 40 mg tablets, Lot no. A01198003I in 900 mL phosphate buffer pH 6.8 at 37°C, Apparatus 2, USP, 75 rpm, Q is (b) (4) % in 15 minutes

Tablet no.	Percent dissolved in minutes				
	5	10	15	30	45
1	(b) (4)				
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
Mean	28.7	83.0	90.3	93.0	94.5
RSD (%)	39.0	8.0	3.0	2.3	1.9
Range	(b) (4)				

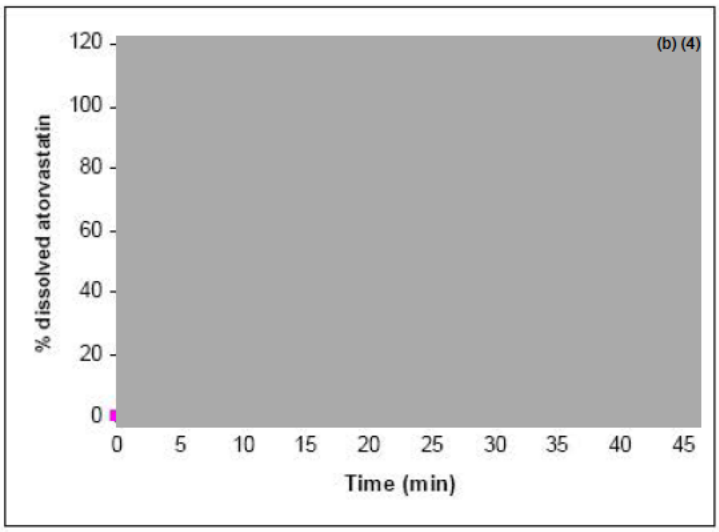


Figure 1: Percent dissolved (mean values) of atorvastatin from:
♦ - Atorvastatin 40 mg tablets, Lot no. A01198003I (1st analysis) and
■ - Atorvastatin 40 mg tablets, Lot No. A01198003I 2nd analysis)
in phosphate buffer pH 6.8, Apparatus 2, USP, 75 rpm

Reviewer's Comments on Firm's Response to Deficiency #2:

- The 1st analysis (dissolution testing) showed one tablet had unusually low % dissolution at 5, 10 and 15 minutes time points causing high coefficient of variation (%RSD) at those time points. The analysis (dissolution test) was repeated at our request.

  In the 2nd analysis (dissolution test) one tablet again showed low % dissolution but now only at the 5 minute time point. However, the dissolution testing is considered acceptable because of the following reasons.

  i) The mean % dissolution profiles from both analyses match (f2= 74.44)
  ii) The %RSD at 10 and 15 minutes is low in the 2nd analysis.
  iii) The %RSD for the 15 minutes is below 10 % in the both analyses.
  iv) The test product met the FDA-recommended specification [NLT (b) (4) (Q) in 15 minutes] in the 2nd analyses at the S1 level.

  The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate buffer, pH 6.8, at 37ºC ± 0.5º C using USP apparatus II (Paddle) at 75 rpm. The test product should meet the following specification:

  NLT (b) (4) (Q) of Atorvastatin Calcium is dissolved in 15 minutes.

- The firm's response to the deficiency #2 is acceptable.

D. Deficiency Comments

None.

E. Recommendations

1. The Division of Bioequivalence (DBE) accepts the fasting bioequivalence (BE) study (Study No. 80018) conducted by **Sandoz Inc** on its Atorvastatin Calcium Tablets, 80 mg, Batch# 30004016/AA3869, comparing it to Pfizer's Lipitor® (Atorvastatin Calcium) Tablets, 80 mg, Batch # 15267V**.**

2. The fed BE study was found acceptable earlier. Cited from the recommendation 2 of page 12 from V:\firmsam\Lek\ltrs&rev\77575N0205.doc - "The single-dose fed bioequivalence study (Study No. AA05473) conducted by **Lek Pharmaceuticals** on its test product, Atorvastatin Calcium Tablets, 80 mg, Lot # 3256108F comparing it to the reference product Lipitor® 80 mg Tablets Lot # 06284V is acceptable .

3. The firm's *in vitro* dissolution testing is adequate. The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate buffer, pH 6.8, at 37ºC ± 0.5º C using USP apparatus II (Paddle) at 75 rpm. The test product should meet the following specification:

NLT [redacted] (Q) of Atorvastatin Calcium is dissolved in 15 minutes.

4. The DBE grants the waiver requests for *in vivo* BE study requirements for the following strengths: (i) 10 mg, (ii) 20 mg, and (iii) 40 mg of the test product, based on criteria set forth in 21 CFR § 320.22 (d) (2).

5. The DBE deems the test product, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, manufactured by Sandoz Inc, to be bioequivalent to the corresponding reference product, Lipitor® (Atorvastatin Calcium) Tablets, 10 mg, 20 mg, 40 mg and 80 mg, manufactured by Pfizer.

The amendment is **adequate**.

APPEARS THIS WAY ON ORIGINAL.

BIOEQUIVALENCE COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 077575

APPLICANT: Sandoz Inc.

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

The Division of Bioequivalence (DBE) has completed its review and has no further questions at this time.

The DBE acknowledges that the dissolution testing for the test product will be conducted in 900 mL of 0.05 M Phosphate Buffer, pH 6.8, at 37°C ± 5°C, using USP apparatus 2 (paddle) at 75 rpm. The test product should meet the following specification:

> Not less than (b) (4) (Q) of the labeled amount of Atorvastatin Calcium in the dosage form is dissolved in 15 minutes.

Please note that the bioequivalence comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalence information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

F. Outcome Page

ANDA: 077575

Productivity:

ID	*Letter Date*	*Productivity Category*	*Sub Category*	*Productivity*	*Subtotal*
11032	03/02/2010	Other	Study Amendment	1	1
				Bean Total:	1

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	LEK PHARMACEUTICALS D D	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LI GONG
04/30/2010

SHRINIWAS G NERURKAR
05/03/2010

HOAINHON N CARAMENICO on behalf of DALE P CONNER
05/07/2010

DIVISION OF BIOEQUIVALENCE REVIEW AN AMENDMENT

ANDA No.	077575		
Drug Product Name	Atorvastatin Calcium Tablets		
Strength(s)	10 mg, 20 mg, 40 mg and 80 mg		
Applicant Name*	Sandoz Inc.		
Address	506 Carnegie Center, Suite 400 Princeton, NJ 08540		
Applicant's Point of Contact	Srinivasa S. Rao, Pharm.D.		
Contact's Telephone Number	609-627-8885		
Contact's Fax Number	609-395-2792		
Original Submission Date(s)	February 18, 2005		
Submission Date(s) of Amendment(s) Under Review	March 11, 2009 (current amendment)		
Reviewer	Li Gong, Ph.D.		
Study Number (s)	80018	AA05474	AA05473
Study Type (s)	Fasting	Fasting (failed study)	Fed
Strength (s)	80 mg	80 mg	80 mg
Clinical Site	Anapharm		
Clinical Site Address	4101 Yonge Street, Suite 600 P.O. Box 222 Toronto (Ontario) CANADA M2P 1N6		
Analytical Site	(b) (4)		
Analytical Site Address			
OVERALL REVIEW RESULT	**INADEQUATE**		
DSI REPORT RESULT	**ADEQUATE**		
Bioequivalence Study Tracking/supporting Document #	**Study / Test Type**	**Strength**	**Review Result**
19	Fasting	80 mg	Inadequate

*The previous ANDA holder, Lek Pharmaceuticals d.d., transferred its business activity to Sandoz Inc. on January 1, 2008.

1 EXECUTIVE SUMMARY

Sandoz Inc. submitted its responses to the deficiency comments made by the Division of Bioequivalence (DBE) in the letter of December 31, 2007. In the original application, the firm submitted the results of fasting and fed bioequivalence (BE) studies comparing its test product, Atorvastatin Calcium Tablets, 80 mg, to the corresponding reference product, Lipitor® (Atorvastatin Calcium) Tablets, 80 mg, and waiver requests of *in vivo*

BE requirements for the lower strengths of the test product, Atorvastatin Calcium Tablets, 10 mg, 20 mg and 40 mg, respectively. The BE studies were designed as a single-dose, semi-replicate, 3-way crossover study in healthy male and female volunteers. The firm's fasting BE study was found not acceptable by the Division of Bioequivalence (DBE) due to its 90% Confidence Interval (CI) of LnCmax being outside the acceptable range of 80-125. The fed BE study was found acceptable. Also, the waiver requests of in vivo BE requirements on its respective lower strengths, 10 mg, 20 mg and 40 mg, were denied due to the deficiencies in the BE study.

As per the DBE's deficiency comments, the firm submitted the results of a new fasting BE study in the current amendment. The firm has manufactured new test batches [Batch #s: A01179803I (10 mg strength), A01196903I (20 mg strength), A01198003I (40 mg strength) and 30004016/AA3869 (new biobatch, 80 mg strength)] and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired.

The fasting BE study was designed as a single-dose, two-way crossover in healthy male and female volunteers. The BE study results are summarized in the table below.

For Atorvastatin†:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
New Fasting Bioequivalence Study (Study No. 80018)					
Parameter	**Test**	**Reference**	**Ratio (%)**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	147342.6	138985.1	1.06	100.65	111.66
AUC∞ (pg*hr /mL)	149924.2	142963.5	1.05	100.10	109.87
Cmax (pg /mL)	34499.03	35521.73	0.97	85.75	110.00

For o-Hydroxy-Atorvastatin†:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
New Fasting Bioequivalence Study (Study No. 80018)					
Parameter	**Test**	**Reference**	**Ratio (%)**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	153062.4	150125.8	1.02	95.20	109.19
AUC∞ (pg*hr /mL)	155209.3	156541.2	0.99	93.88	104.71
Cmax (pg /mL)	23976.97	25249.26	0.95	83.10	108.51

For p-Hydroxy-Atorvastatin†:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
New Fasting Bioequivalence Study (Study No. 80018)					
Parameter	**Test**	**Reference**	**Ratio (%)**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	18505.50	16167.13	1.14	106.81	122.66
AUC∞ (pg*hr /mL)	22120.39	20140.93	1.10	103.32	116.75
Cmax (pg /mL)	1139.48	901.71	1.26	113.69	140.47

†Reviewer-calculated results from the current fasting BE study.

The firm's dissolution testing data with the FDA-recommended method are acceptable for the 10 mg, 20 mg and 80 mg strengths. The test product of these strengths meets the data driven FDA-recommended specification of NLT (b) (4) Q) in 15 min at the S1 level. However, for the 40 mg strength test product, one tablet had unusually low dissolution at 5, 10 and 15 min which resulted in very high CV% at these sampling time points. In addition, the 40 mg test product does not meet the specification of NLT (b) (4) % (Q) in 15 min. To confirm firm's data, the firm is advised to repeat the dissolution testing using the FDA-recommended method for the 40 mg strength only. The DBE will set the specification for the test product after reviewing the additional dissolution data. The dissolution testing is **inadequate.**

The firm's fasting BE study is **inadequate** due to the deficiency related to the analytical parts of the study. The complete analytical raw numerical data of all sample reassays were not submitted. The firm should submit such data.

In addition, the firm has revised its manufacturing processes when making new batches of the test products. Although the firm submitted an acceptable fed BE study for the test product prior to the manufacturing changes, the firm did not submit a new fed study on the new batch of the products. However, since the firm has only changed the manufacturing processes, but not the formulation of the test product, the changes are considered equivalent to Level 3 SUPAC manufacturing process changes, and a new fasting BE study conducted on the new batch of the highest strength is considered adequate by the DBE at this time.

The waiver requests for in vivo BE study requirements for the firm's lower strengths of the test product, 10 mg, 20 mg, 40 mg can NOT be granted at this time, pending firm's acceptable fasting BE study.

No Division of Scientific Investigations (DSI) inspection is pending or necessary. The clinical site was last inspected for the ANDA 90-486 (routine) on 1/23/2009 with the result of VAI and the analytical site was last inspected for the (b) (4) (routine) on (b) (4) with the result of NAI.

The amendment is **inadequate.**

2 TABLE OF CONTENTS

1 EXECUTIVE SUMMARY 1
2 TABLE OF CONTENTS 4
3 BACKGROUND 4
4 REVIEW OF AMENDMENT SUBMISSION 5
5 SUBMISSION SUMMARY 8
5.1 Drug Product Information 8
5.2 PK/PD Information 9
5.3 OGD Recommendations for Drug Product 11
5.4 Contents of Submission 12
5.5 Pre-Study Bioanalytical Method Validation 12
5.6 In Vivo Studies 15
5.7 Formulation 23
5.8 In Vitro Dissolution 23
5.9 Waiver Request(s) 24
5.10 Deficiency Comments 24
5.11 Recommendations 24
5.12 Comments for Other OGD Disciplines 25
6 APPENDIX 26
6.1 Individual Study Reviews 26
6.1.1 Fasting Bioequivalence Study 26
6.1.1.1 Study Design 26
6.1.1.2 Clinical Results 29
6.1.1.3 Bioanalytical Results 33
6.1.1.4 Pharmacokinetic Results 35
6.2 Formulation Data (Adapted from firm's Formulation Data Table) 47
6.3 Dissolution Data 50
6.4 SAS Output 55
6.4.1 Fasting Study Data 55
6.4.2 Fasting Study Output 86
6.5 Attachment 110
6.6 Outcome Page 144

3 BACKGROUND

1. The firm submitted its original application on February 18, 2005. The firm conducted the fasting and fed BE studies on its test product, Atorvastatin Calcium Tablets, 80 mg, comparing it to the corresponding reference product, Lipitor® (Atorvastatin Calcium) Tablet, 80 mg, and also submitted waiver requests of *in vivo* BE requirements for the lower strengths of the test product, 10 mg, 20 mg and 40 mg. The fed BE study was found acceptable, however, the fasting BE study was found not acceptable because the 90% of confidence interval (CI) of log transformed Cmax of Atorvastatin in the fasting study was outside the acceptable range of [80.00-125.00%] (firm's LnCmax was 98.5-126.72%). Also, the biowaiver requests for Atorvastatin Calcium Tablets, 10 mg, 20 mg and 40 mg, respectively were denied due to unacceptable fasting BE study (V:\firmsam\Lek\ltrs&rev\77575N0205.doc).

2. The firm was advised to address the deficiencies related to the statistical analyses of the failed fasting BE study [DARRTS- 03/05/2007: REV-BIOEQ-01 (General Review)].

3. On April 4, 2007, the firm submitted an amendment in response to the DBE's deficiency letter dated 03/17/2007 and an audit report (prepared by (b) (4)) on two BE studies (AA05474 and AA05473) conducted and analyzed at (b) (4) ((b) (4) The audit report was accepted by the DBE whereas the amendment was found incomplete since the firm's response on the statistical analyses of the failed fasting study data was incomplete [DARRTS- 12/20/2007: REV-BIOEQ-01 (General Review)].

4. The firm has manufactured new test batches [Batch#s: 001179803I, 001196903I, 001198003I and 30004016/AA3869 (new biobatch)] and used new reference batch (Batch #15267V) for the new fasting BE study because the original batches of both the test and RLD products have expired. These new batches were manufactured using revised manufacturing processes (please see the attachment section for details).

5. In the current amendment, the firm submitted the data of a new fasting BE study using the new batches of the test and reference products of Atorvastatin Calcium Tablets. In addition, the firm also submitted comparative dissolution data of the new batches of the test (four new batches including the new biobatch) and reference (only one batch which was used in the new fasting BE study) products using the FDA-recommended method.

4 REVIEW OF AMENDMENT SUBMISSION

Deficiency #1: *Your study uses a two-treatment, three-period replicated crossover design. Your statistical analysis which did not include the subject-by-formulation interaction term is therefore not appropriate. In your analysis, the 90% confidence intervals were computed using the wrong error term. Our analysis, by modifying your proc mixed statements (to include the term subj*trt (seq)) and using the full dataset (i.e., all three periods), showed a statistically significant subject-by-formulation interaction (p = 0.0161 per REML fitting method) and 90% confidence intervals of 98.47% - 126.70% for Cmax. This result is similar to that obtained using the method described in the guidance (which also allows for the possibility of subject-by-formulation interaction).*

Deficiency #2: *Furthermore, your analysis, based on only the data from periods 1 and 2, 'Per (1,2)', is not acceptable. Using dataset 'Per (1,2)' is not an acceptable scenario due to artificially deleting the measures from the third period with no scientific reason. In addition, if using dataset 'Per (1,2)' is to be considered, then dataset 'Per (1,3)' should be checked too. The upper bound of the 90% confidence interval for dataset 'Per (1,3)' is 132.131% which is greater than the 125% bioequivalence limit.*

Deficiency #3: *Regarding your statement that " Therefore, the same approach with regards to the intra-variability estimation and SAS codes as for a 2-way crossover design had been identified a priori as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the protocol.", please note that the agency would*

not accept the results of an inappropriate analysis based on an unsuitable statistical analysis method mentioned in the protocol.

Firm's Responses to Deficiency #1, #2 and #3: "Due to borderline results of fasted study AA05474, a new fasted bioequivalence study with a protocol number 80018 was performed to compare the rate and extent of absorption of atorvastatin 80 mg tablet (test) versus Lipitor® (reference), administered as 1 x 80 mg tablet under fasting conditions. The study design was single dose, bioequivalence, open-label, randomized, 2-way crossover with 80 healthy adult male or female subjects. Washout period was 14 days.

The bioavailability of Atorvastatin calcium 80 mg tablet (manufactured by LEK Pharmaceuticals d.d., Slovenia) (Lot No.: 30004016) was compared to the reference atorvastatin calcium 80 mg tablet (Lipitor® manufactured by Pfizer Ireland Pharmaceuticals, Ireland for Pfizer Inc., USA) (Lot No. 15267V) under fasting conditions.

The following standard was used for bioequivalence: for atorvastatin, 90% geometric confidence interval of the ratio (T/R) of least-squares means from the ANOVA of the ln-transformed AUC0_inf, AUC0-t, and Cmax should be within 80.00% to 125.00%. Results for atorvastatin are presented in Table 1. Data from o-hydroxy-atorvastatin and p-hydroxy-atorvastatin were reported and presented as supportive data."

Table 1. Statistical Summary of the Comparative Bioavailability Data for Atorvastatin

Atorvastatin calcium Dose (1 x 80 mg) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals				
Fasted Bioequivalence Study (Study No. 80018)				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC0-t	147342.59 pg·h/mL	138985.06 pg·h/mL	106.01%	100.65% to 111.66%
AUC∞	149924.21 pg·h/mL	142963.45 pg·h/mL	104.87%	100.10% to 109.87%
Cmax	34499.03 pg/mL	35521.73 pg/mL	97.12%	85.75% to 110.00%

Based on these results, it can be concluded that the test atorvastatin calcium is bioequivalent to the reference Lipitor® following an 80 mg dose under fasting conditions."

Reviewer's Comments on Firm's Response to Deficiency #1:

- Please refer to the Section 6: Appendix section of the amendment for information regarding the firm's newly conducted fasting BE study of the test product (Study No. 80018).

- The reviewer completed the review of the currently conducted new fasting BE study and found it **inadequate**.

- The firm conducted comparative dissolution testing on four strengths of Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, using the FDA-recommended dissolution method. The firm's dissolution testing data are acceptable for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. The test product of these strengths meets the data driven FDA-recommended specification of NLT (b) (4) (Q) in 15 min at the S1 level. However, for the 40 mg (Lot # A01198003I) strength test product, one tablet had unusually low dissolution at 5, 10 and 15 min which resulted in very high CV% at these sampling time points. In addition, the 40 mg test product does not meet the specification of NLT (b) (4) (Q) in 15 min. To confirm firm's data, the firm is advised to repeat the dissolution testing using the FDA-recommended method for the 40 mg strength only. The DBE will set the specification for the test product after evaluating the additional dissolution data. The dissolution testing is **inadequate.**

- The firm did not submit complete raw numerical data of study sample assay and reassay runs. The firm should submit complete raw numerical data which should include the peak area/height for the drug, peak area/height for the internal standard, the ratio of the peak area/height for the drug to the peak area for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each reassayed sample, calibration standard samples, and quality control samples.

  It is noted that the firm's manufacturing processes have been revised and the current batches of the test product including the current biobatch (used in new fasting BE study; Study No. 80018) were produced through a different manufacturing process ("the proposed optimized manufacturing process") from that previously submitted [(used in prior fed BE study (Study No. AA 05473)]. Although the firm submitted an acceptable fed BE study for the test product prior to the manufacturing changes, the firm did not submit a new fed study on the new batch of the products. However, since the firm has only changed the manufacturing processes, but not the formulation of the test product, the changes are considered equivalent to Level 3 SUPAC manufacturing process changes, and a new fasting BE study conducted on the new batch of the highest strength is considered adequate by the DBE at this time.

- Thus, the firm's responses to Deficiency #1, #2 and #3 are inadequate.

- The amendment is **inadequate**.

5 SUBMISSION SUMMARY

5.1 Drug Product Information[1]

Test Product	Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg
Reference Product	Lipitor® (Atorvastatin calcium) Tablets, 10 mg, 20 mg, 40 mg and 80 mg
RLD Manufacturer	Pfizer, Inc.
NDA No.	20-702
RLD Approval Date	December 17, 1996 (for 10 mg, 20 mg, and 40 mg strengths); April 7, 2000 (for 80 mg strength)
Indication	Lipitor®'s indications are as follows: **(1) Prevention of cardiovascular disease** In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, LIPITOR is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, LIPITOR is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina **(2) Hypercholesterolemia** LIPITOR is indicated: • as an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial

[1] RLD Labeling

	and nonfamilial) and mixed dyslipidemia *(Fredrickson* Types IIa and IIb); • as an adjunct to diet for the treatment of patients with elevated serum TG levels*(Fredrickson* Type IV); • for the treatment of patients with primary dysbetalipoproteinemia *(Fredrickson* Type III) who do not respond adequately to diet; • to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable; • as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: - there is a positive family history of premature cardiovascular disease or - two or more other CVD risk factors are present in the pediatric patient

5.2 PK/PD Information[2, 3]

Bioavailability & Absorption	Atorvastatin is rapidly absorbed after oral administration. The absolute bioavailability of atorvastatin (parent drug) is approximately 14%. The low systemic availability is attributed to presystemic clearance in gastrointestinal mucosa and/or hepatic first-pass metabolism.
Food Effect	Although food decreases the rate and extent of drug absorption by approximately 25% and 9%, respectively, reduction is similar whether atorvastatin is given with or without food.
Tmax	1 – 2 hours
Metabolism	Atorvastatin is extensively metabolized to ortho- and parahydroxylated derivatives and various beta-oxidation products which account for approximately70% of the circulating HMG-CoA reductase inhibitory activity. *In vitro* inhibition of HMG-CoA reductase by ortho- and parahydroxylated metabolites is equivalent to that of atorvastatin. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites. *In vitro* studies suggest the importance of atorvastatin metabolism by cytochrome P450 3A4, consistent with increased plasma concentrations of atorvastatin in humans following coadministration with erythromycin, a known inhibitor of this isozyme. In animals, the ortho-hydroxy metabolite undergoes further glucuronidation.

[2] Online-Clinical Pharmcology http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=672&sec=monphar
[3] Online- Thompson MICROMEDEX http://csi.micromedex.com/DATA/TM/TM653.HTM?Top=Yes#8

Excretion	Atorvastatin and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism; however, the drug does not appear to undergo enterohepatic recirculation. Less than 2% of a dose of atorvastatin is recovered in urine following oral administration.
Half-life	14 hours (parent, atorvastatin) 20 – 30 hours (active metabolites)
Drug Specific Issues (if any)	**WARNINGS AND PRECAUTIONS:** • HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Persistent elevations (>3 times the upper limit of normal [ULN] occurring on 2 or more occasions) in serum transaminases occurred in 0.7% of patients who received atorvastatin in clinical trials. The incidence of these abnormalities was 0.2%, 0.2%, 0.6%, and 2.3% for 10, 20, 40, and 80 mg, respectively. • It is recommended that liver function tests be performed prior to and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (e.g., semiannually) thereafter. Liver enzyme changes generally occur in the first 3 months of treatment with atorvastatin. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. Should an increase in ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of atorvastatin is recommended. • Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin and with other drugs in this class. • Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures). • Before instituting therapy with atorvastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients, and to treat other underlying medical problems

5.3 OGD Recommendations for Drug Product

Number of studies recommended:	2, fasting and fed

1.	**Type of study:**	Fasting
	Design:	Single-dose, two-treatment, two-period crossover in-vivo
	Strength:	80 mg
	Subjects:	Normal healthy males and females, general population
	Additional Comments:	None
2.	**Type of study:**	Fed
	Design:	Single-dose, two-treatment, two-period crossover in-vivo
	Strength:	80 mg
	Subjects:	Normal healthy males and females, general population
	Additional Comments:	None

Analytes to measure (in plasma/serum/blood):	Atorvastatin, ortho- and parahydroxylated metabolites of atorvastatin. The ortho- and parahydroxylated metabolites of atorvastatin are formed by presystemic metabolism and contribute meaningfully to efficacy. For the metabolites, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.
Bioequivalence based on (90% CI):	90% CI of Atorvastatin
Waiver request of *in-vivo* testing:	10 mg, 20 mg and 40 mg
Source of most recent recommendations*:	Individual Product Bioequivalence Recommendations: Atorvastatin, May 2008 (Final) http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm082580.pdf

Summary of OGD or DBE History	The DBE has reviewed the following ANDAs for Atorvastatin Calcium Tablets: • ANDA #76-477 (Ranbaxy Labs) • ANDA #78-773 (Teva) • ANDA #90-548 (Apotex) • ANDA #91-226 (Matrix Labs) • ANDA #77-575 (Sandoz Inc, current amendment) The following studies are recommended to establish BE studies of atorvastatin tablets: a) single-dose, two-way crossover fasting *in-vivo* BE study comparing Atorvastatin CalciumTablets, 80 mg, to the RLD, Lipitor® Tablets, 80 mg. b) single-dose, two-way crossover fed *in-vivo* BE study comparing Atorvastatin Calcium Tablets, 80 mg, to RLD, Lipitor® Tablets, 80 mg. The firms are requested to measure atorvastatin, and ortho- and parahydroxylated metabolites of atorvastatin. Simvastatin Tablets, 10 mg, 20 mg, and 40 mg, may be considered for waivers of *in-vivo* BE testing based on (1) acceptable BE studies on the 80 mg strength, (2) acceptable dissolution testing of the 10 mg, 20 mg, 40 mg, and 80 mg strengths, and (3) proportional similarity in the formulations of 10 mg, 20 mg, 40 mg, and 80 mg strengths

5.4 Contents of Submission

Study Types	Yes/No?	How many?
Single-dose fasting	No	1
Single-dose fed	No	
Steady-state	Yes	
In vitro dissolution	Yes	4
Waiver requests	Yes	1
BCS Waivers	No	
Clinical Endpoints	No	
Failed Studies	No	
Amendments	No	1

5.5 Pre-Study Bioanalytical Method Validation

Information Requested	Data
Bioanalytical method validation report location	Bioanalytical report section 16.2.5.3
Analyte	Atorvastatin p-Hydroxy-Atorvastatin o-Hydroxy-Atorvastatin
Internal standard (IS)	Atorvastatin-d_5 p-Hydroxy-Atorvastatin-d_5 o-Hydroxy-Atorvastatin-d_5

Method description	This method involves the extraction of Atorvastatin, p-Hydroxy-Atorvastatin and o-Hydroxy-Atorvastatin and their internal standard from human EDTA plasma using an automated liquid-liquid extraction (Liquid handling system) with methyl tert-butyl ether (MTBE) according to SOP ANI 9519.01. Samples are kept frozen at -80ºC prior to analysis and 0.100 mL of human EDTA plasma was used for analysis.
Limit of quantitation (pg/mL)	**Atorvastatin:** 50.16 **p-Hydroxy-Atorvastatin:** 50.40 **o-Hydroxy-Atorvastatin:** 50.08
Average Recovery of drug (%)	**Atorvastatin:** 94.56, 93.56, 92.67 **p-Hydroxy-Atorvastatin:** 89.17, 90.63, 87.70 **o-Hydroxy-Atorvastatin:** 92.86, 96.43, 94.45
Average Recovery of IS (%)	**Atorvastatin:** 75.17 **p-Hydroxy-Atorvastatin:** 86.12 **o-Hydroxy-Atorvastatin:** 81.85
Standard Curve Concentrations (pg/mL)	**Atorvastatin:** 50.16 to 50160.00 **p-Hydroxy-Atorvastatin:** 50.40 to 5040.00 **o-Hydroxy-Atorvastatin:** 50.08 to 50080.00
QC concentrations (pg/mL)	**Atorvastatin:** QC1: 150.48 QC2: 15048.00 QC3: 35112.00 **p-Hydroxy-Atorvastatin:** QC1: 151.20 QC2: 1512.00 QC3: 3528.00 **o-Hydroxy-Atorvastatin:** QC1: 150.24 QC2: 15024.00 QC3: 35056.00
QC Intraday precision range (%)	**Atorvastatin:** 1.61 to 5.06 **p-Hydroxy-Atorvastatin:** 1.77 to 5.28 **o-Hydroxy-Atorvastatin:** 1.72 to 11.26
QC Intraday accuracy range (%)	**Atorvastatin:** 90.83 to 104.17 **p-Hydroxy-Atorvastatin:** 95.67 to 103.57 **o-Hydroxy-Atorvastatin:** 92.14 to 102.84
QC Interday precision range (%)	**Atorvastatin:** 2.87 to 5.28 **p-Hydroxy-Atorvastatin:** 3.59 to 6.50 **o-Hydroxy-Atorvastatin:** 2.28 to 6.73
QC Interday accuracy range (%)	**Atorvastatin:** 97.07 to 101.60 **p-Hydroxy-Atorvastatin:** 96.33 to 101.30 **o-Hydroxy-Atorvastatin:** 97.33 to 101.20
Bench-Top Stability (hrs)	**Atorvastatin:** 22 hours at 4ºC, 15 hours at 4ºC (Fortified with Lactone) **p-Hydroxy-Atorvastatin:** 24 hours at 4ºC, 15 hours at 4ºC (Fortified with Lactone) **o-Hydroxy-Atorvastatin:** 22 hours at 4ºC, 9 hours at 4ºC (Fortified with Lactone)
Stock Stability (days)	**Atorvastatin:** Analyte: 323 days at -80ºC IS: 350 days at -80ºC **p-Hydroxy-Atorvastatin: Analyte:** 323 days at -80ºC IS: 350 days at -80ºC **o-Hydroxy-Atorvastatin: Analyte:** 323 days at -80ºC IS: 350 days at -80ºC
Processed stability (hrs)	**Atorvastatin**: 16 hours at room temperature and 64 hours at 4°C, 15 hours at room temperature and 64 hours at 4°C (Fortified with lactone) **p-Hydroxy-Atorvastatin:** 19 hours at room temperature and 63 hours at 4°C, 21 hours at room temperature and 63 hours at 4°C (Fortified with lactone) **o-Hydroxy-Atorvastatin:** 20 hours at room temperature and 65 hours at 4°C, 21 hours at room temperature and 65 hours at 4°C (Fortified with lactone)

Freeze-thaw stability (cycles)	**Atorvastatin:** 4 cycles (-20ºC/-80ºC), 4 cycles (-80ºC) Fortified with Lactone **p-Hydroxy-Atorvastatin:** 4 cycles (-20ºC/-80ºC), 4 cycles (-80ºC) Fortified with Lactone **o-Hydroxy-Atorvastatin:** 4 cycles (-20ºC/-80ºC), 4 cycles (-80ºC) Fortified with Lactone
Long-term storage stability (days)	**Atorvastatin:** 363 days at -80ºC (EDTA K_3), 254 days at -80ºC (EDTA K_2), 91 days at -80°C (Fortified with lactone) **p-Hydroxy-Atorvastatin:** 363 days at -80ºC (EDTA K_3), 254 days at -80ºC (EDTA K_2), 91 days at -80°C (Fortified with lactone) **o-Hydroxy-Atorvastatin:** 363 days at -80ºC (EDTA K_3), 254 days at -80ºC (EDTA K_2), 91 days at -80°C (Fortified with lactone)
Dilution integrity	**Atorvastatin:** QC3 diluted 1/2: CV (%) 3.82 Nominal (%) 101.67 DQC diluted 1/20: CV (%) 4.03 Nominal (%) 97.36 **p-Hydroxy-Atorvastatin:** QC3 diluted 1/2: CV (%) 5.67 Nominal (%) 103.99 DQC diluted 1/20: CV (%) 3.49 Nominal (%) 97.66 **o-Hydroxy-Atorvastatin:** QC3 diluted 1/2: CV (%) 3.60 Nominal (%) 100.01 DQC diluted 1/20: CV (%) 2.39 Nominal (%) 98.55
Selectivity	No interfering peaks noted in blank plasma samples

SOPs submitted	Yes
Bioanalytical method is acceptable	Acceptable

Comments on the Pre-Study Method Validation:

- The long term storage data for respective Atorvastatin, p-Hydroxy-Atorvastatin and o-Hydroxy-Atorvastatin of 363 days exceeds the storage period for the samples of the fasting BE study (91 days).
- The anticoagulant used in the pre-study validation was K_3EDTA and is the same as used in within study analysis. The pre-study validation data are acceptable.

5.6 In Vivo Studies

Table 1A. Summary of Bioavailability Studies for Atorvastatin

Study Ref. No.	Study Objective	Study Design	Treatments (Dose, Dosage Form, Route) [Product ID]	Subjects No. (M/F) Type Age: mean (Range)	Mean Parameters (+/-SD)						Study Report Location
					Cmax (pg/mL)	Tmax (hr)	AUC0-t (pg·h/mL)	AUC∞ (pg·h/mL)	T½ (hr)	Kel (hr-1)	
80018	Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following a 80 mg Dose in Healthy Subjects Under Fasting Conditions	Randomized single-dose crossover	Atorvastatin calcium (1 x 80 mg tablet, p.o.) [Lot/Batch #30004016]	72 completing (70 M / 2 F) Healthy subjects Age (years) = 35 (18-54) Data set for statistical analysis = 72	40041.84 (26091.86)	1.76 (1.04) 1.67 (1.00)*	162499.70 (92643.50)	165065.23 (92930.32)	12.20 (3.31)	0.0605 (0.0147)	5.3.1.2.1
			Lipitor® (1 x 80 mg tablet, p.o.) [Lot/Batch # 15267V]		40663.51 (21437.13)	1.09 (0.94) 0.750 (0.830)*	149122.93 (60120.43)	153180.19 (61733.53)	12.86 (4.80)	0.0596 (0.0173)	5.3.1.2.1

* Median (interquartile range)

Table 1B. Summary of Bioavailability Studies for o-Hydroxy-Atorvastatin

Study Ref. No.	Study Objective	Study Design	Treatments (Dose, Dosage Form, Route) [Product ID]	Subjects No. (M/F) Type Age: mean (Range)	Mean Parameters (+/-SD)						Study Report Location
					Cmax (pg/mL)	Tmax (hr)	AUC0-t (pg·h/mL)	AUC∞† (pg·h/mL)	T½† (hr)	Kel† (hr-1)	
80018	Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following a 80 mg Dose in Healthy Subjects Under Fasting Conditions	Randomized single-dose crossover	Atorvastatin calcium (1 x 80 mg tablet, p.o.) [Lot/Batch # 30004016]	72 completing (70 M / 2 F) Healthy subjects Age (years) = 35 (18-54) Data set for statistical analysis = 72	26729.28 (14278.29)	2.12 (1.16) 1.67 (1.17)*	166063.46 (86459.17)	167800.05 (86386.42)	12.43 (4.07)	0.0612 (0.0187)	5.3.1.2.1
			Lipitor® (1 x 80 mg tablet, p.o.) [Lot/Batch # 15267V]		29400.60 (13272.51)	1.59 (1.96) 1.00 (1.25)*	161804.97 (68927.24)	167235.95 (71678.27)	13.25 (4.32)	0.0568 (0.0156)	5.3.1.2.1

* Median (interquartile range) † For these parameters, N=71

Table 1C. Summary of Bioavailability Studies for p-Hydroxy-Atorvastatin

Study Ref. No.	Study Objective	Study Design	Treatments (Dose, Dosage Form, Route) [Product ID]	Subjects No. (M/F) Type Age: mean (Range)	Mean Parameters (+/-SD)						Study Report Location
					Cmax (pg/mL)	Tmax (hr)	AUC0-t (pg·h/mL)	AUC∞† (pg·h/mL)	T½† (hr)	Kel† (hr-1)	
80018	Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following a 80 mg Dose in Healthy Subjects Under Fasting Conditions	Randomized single-dose crossover	Atorvastatin calcium (1 x 80 mg tablet, p.o.) [Lot/Batch # 30004016]	72 completing (70 M / 2 F) Healthy subjects Age (years) = 35 (18-54) Data set for statistical analysis = 72	1416.24 (1387.76)	5.82 (3.03) 4.50 (4.13)*	21929.90 (16678.77)	25533.87 (18257.21)	23.00 (9.39)	0.0346 (0.0124)	5.3.1.2.1
			Lipitor® (1 x 80 mg tablet, p.o.) [Lot/Batch # 15267V]		1076.73 (671.45)	7.59 (8.93) 6.50 (7.13)*	18647.83 (10864.38)	22764.86 (12403.21)	24.61 (10.19)	0.0319 (0.0103)	5.3.1.2.1

* Median (interquartile range) † For these parameters, N=63

Table 2. Statistical Summary of the Comparative Bioavailability Data Calculated by the Reviewer

For Atorvastatin:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
Fasting Bioequivalence Study [Study No. 80018]					
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	147342.6	138985.1	1.06	100.65	111.66
AUC∞ (pg*hr /mL)	149924.2	142963.5	1.05	100.10	109.87
Cmax (pg /mL)	34499.03	35521.73	0.97	85.75	110.00

For o-Hydroxy-Atorvastatin:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
Fasting Bioequivalence Study [Study No. 80018]					
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	153062.4	150125.8	1.02	95.20	109.19
AUC∞ (pg*hr /mL)	155209.3	156541.2	0.99	93.88	104.71
Cmax (pg /mL)	23976.97	25249.26	0.95	83.10	108.51

For para-Hydroxy-Atorvastatin:

Atorvastatin Calcium Tablets 80 mg Dose (1 x 80 mg), N=72 (Male= 70 and Female= 2) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals					
Fasting Bioequivalence Study [Study No. 80018]					
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	18505.50	16167.13	1.14	106.81	122.66
AUC∞ (pg*hr /mL)	22120.39	20140.93	1.10	103.32	116.75
Cmax (pg /mL)	1139.48	901.71	1.26	113.69	140.47

Table 3A. Reanalysis of Study Samples for Atorvastatin

Study No. 80018 Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following an 80 mg Dose in Healthy Subjects under Fasting Conditions. Additional information in tables 5 and 8 of bioanalytical report								
Reason why assay was repeated	**Number of samples reanalyzed**				**Number of recalculated values used after reanalysis**			
	Actual number		**% of total assays**		**Actual number**		**% of total assays**	
	T	**R**	**T**	**R**	**T**	**R**	**T**	**R**
Pharmacokinetic[1]	0	0	0.00	0.00	0	0	0.00	0.00
Unacceptable internal standard response	1	1	0.03	0.03	1	1	0.03	0.03
Incomplete analysis	3	7	0.08	0.18	3	6	0.08	0.15
Sample concentration above upper limit of quantification	28	23	0.71	0.59	28	23	0.71	0.59
Sample reanalyzed to obtain confirming value	0	1	0.00	0.03	0	1	0.00	0.03
Sample repeated or reinjected by error	1	0	0.03	0.00	0	0	0.00	0.00
Total	33	32	0.84	0.82	33	31	0.79	0.79

Table 3B. Reanalysis of Study Samples for o-Hydroxy-Atorvastatin

Study No. 80018 Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following an 80 mg Dose in Healthy Subjects under Fasting Conditions. Additional information in tables 7 and 10 of bioanalytical report								
Reason why assay was repeated	Number of samples reanalyzed				Number of recalculated values used after reanalysis			
	Actual number		% of total assays		Actual number		% of total assays	
	T	R	T	R	T	R	T	R
Pharmacokinetic[1]	0	0	0.00	0.00	0	0	0.00	0.00
Poor Chromatography	2	2	0.05	0.05	2	2	0.05	0.05
Unacceptable internal standard response	1	2	0.03	0.05	1	2	0.03	0.05
Incomplete analysis	3	7	0.08	0.18	3	7	0.08	0.18
Sample concentration above upper limit of quantification	12	7	0.31	0.18	12	7	0.31	0.18
Rejected sample dilution	1	0	0.03	0.00	1	0	0.03	0.00
Sample reassayed or reinjected by error	72	68	1.84	1.74	70	68	1.79	1.74
Total	91	86	2.33	2.20	88	86	2.25	2.20

Table 3C. Reanalysis of Study Samples for para-Hydroxy-Atorvastatin

Study No. 80018 Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following an 80 mg Dose in Healthy Subjects under Fasting Conditions. Additional information in tables 6 and 9 of bioanalytical report								
Reason why assay was repeated	Number of samples reanalyzed				Number of recalculated values used after reanalysis			
	Actual number		% of total assays		Actual number		% of total assays	
	T	R	T	R	T	R	T	R
Pharmacokinetic[1]	0	0	0.00	0.00	0	0	0.00	0.00
Poor Chromatography	1	1	0.03	0.03	1	1	0.03	0.03
Unacceptable internal standard response	1	1	0.03	0.03	1	1	0.03	0.03
Incomplete analysis	3	7	0.08	0.18	3	7	0.08	0.18
Sample concentration above upper limit of quantification	7	0	0.18	0.00	7	0	0.18	0.00
Total	12	9	0.31	0.23	12	9	0.31	0.23

1 - If no repeats were performed for pharmacokinetic reasons, insert "0.0."

[T] Atorvastatin calcium 80 mg film-coated tablet (1 x 80 mg tablet per period), Lek Pharmaceuticals d.d., (Slovenia) Lot: 30004016

[R] Atorvastatin calcium 80 mg film-coated tablet (1 x 80 mg tablet per period), Lipitor®, Pfizer Inc., (USA) Lot: 15267V

Did use of recalculated plasma concentration data change study outcome?

The reviewer is not able to verify the study sample reanalysis data because the firm did not submit a complete list of raw numerical data for all bioanalytical reassays conducted in its new fasting BE study (Study No. 80018). Also, the reassay coded as "Sample reanalyzed to obtain confirming value" is considered as PK repeat. The reviewer will re-evaluate the new fasting study after receiving a complete set of the firm's reassay raw data.

Comments from the Reviewer:

- The firm did not submit complete raw numerical data of study sample reassays for the repeat runs. The firm should submit complete raw numerical data of all sample reanalysis including the peak area for the drug, peak area for the internal standard, the ratio of the peak area for the drug to the peak area for the internal standard, dilution factor (if any), and the corresponding concentration for each reassayed sample, calibration standard concentration samples, and quality control samples.

- The reassay coded as "Sample reanalyzed to obtain confirming value" is considered as PK repeat. The reviewer will re-evaluate the firm's new fasting study after receiving a complete set of its reassay raw data.

5.7 Formulation

Location in appendix	Refer to Formulation Data in Section 6.2
If a tablet, is the RLD scored?	No
If a tablet, is the test product biobatch scored	No
Is the formulation acceptable?	Yes
If not acceptable, why?	

5.8 In Vitro Dissolution

Location of DBE Dissolution Review	V:firmsam\lek \ltrs&rev\77575D0205.doc
Source of Method (USP, FDA or Firm)	FDA
Medium	0.05 M Phosphate Buffer, pH 6.8
Volume (mL)	900 mL
USP Apparatus type	II (paddle)
Rotation (rpm)	75 rpm
FDA specification	(b) (4) (Q) of the amount of Atorvastatin is dissolved in 15 minutes.
If a modified-release tablet, was testing done on ½ tablets?	N/A
F2 metric calculated?	No
If no, reason why F2 not calculated	Rapidly dissolving
Is method acceptable?	**Incomplete**
If not then why?	Pending the firm's additional dissolution testing data

Reviewer's notes:

The firm has manufactured a new test batch (Batch # 30004016/AA3869) and used new reference batch (Batch # 15267V) for the conductance of new fasting BE study, since the original batches of both the test and RLD products have expired. Thus the firm performed comparative dissolution testing on the new batches of the 80 mg strength (new biobatches) of both the test and the reference products of Atorvastatin Calcium Tablets. The reviewer noted that the firm perform dissolution testing on the lower strengths (e.g. 10 mg, 20 mg and 40 mg strengths) of new batches of the test product (Lot Nos: A01179803I, A01196903I and A01198003I), however used prior dissolution data from old batches of the respective 10 mg, 20 mg and 40 mg strengths of the reference product (Batch Nos: 10474V, 0483024 and 0404024) to compare with new dissolution testing data of the corresponding test product. The firm's dissolution testing data with the FDA-recommended method are acceptable for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. The test product of these strengths meets the data driven FDA-recommended specification of NLT (b) (6) (Q) in 15 min at the S1 level. However, for the 40 mg (Lot # A01198003I) strength test product, one tablet

had unusually low dissolution at 5, 10 and 15 min which resulted in very high CV% at these sampling time points. In addition, the 40 mg test product does not meet the specification of NLT [redacted] (b) (4) (Q) in 15 min. To confirm firm's data, the firm is advised to repeat the dissolution testing using the FDA-recommended method for the 40 mg strength only. The DBE will set the specification for the test product after evaluating the additional dissolution data. The dissolution testing is **inadequate.**

5.9 Waiver Request(s)

Strengths for which waivers are requested	10 mg, 20 mg and 40 mg
Proportional to strength tested in vivo?	Yes
Is dissolution acceptable?	Incomplete
Waivers granted?	**WAIVER DENIED**
If not then why?	Pending the firm's acceptable BE studies and additional dissolution testing data

5.10 Deficiency Comments

1. For the firm's fasting BE study (Study No. 80018), the firm did not submit complete raw numerical data of study sample assay and reassay runs. The firm should submit complete raw numerical data which should include the peak area/height for the drug, peak area/height for the internal standard, the ratio of the peak area/height for the drug to the peak area for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each reassayed sample, calibration standard samples, and quality control samples.

2. The firm's dissolution testing data with the FDA-recommended method are adequate only for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. However, for the 40 mg (Lot # A01198003I) strength test product, one tablet had unusually low dissolution at 5, 10 and 15 min which resulted in very high CV% at these sampling time points. To confirm firm's data, the firm is advised to repeat the dissolution testing using the FDA-recommended method for the 40 mg strength only. The DBE will set the specification for the test product after evaluating the additional dissolution data.

5.11 Recommendations

1. The fasting BE study No. 80018 conducted by Sandoz Inc., on its Atorvastatin Calcium Tablets, 80 mg, Batch# 30004016/AA3869, comparing it to Pfizer's Lipitor® (Atorvastatin Calcium) Tablets, 80 mg, Batch # 15267V, is **inadequate** due to the above mentioned Deficiency No. 1.

2. The *in vitro* dissolution testing on the 40 mg strength of the test product conducted by the firm, using the FDA-recommended dissolution method, is **inadequate** due to the above mentioned Deficiency No. 2.

3. The waiver request for in vivo BE study requirements for the firm's lower strengths of the test product, 10 mg, 20 mg and 40 mg, can NOT be granted at this time due to the above mentioned deficiencies.

The amendment is **inadequate**.

5.12 Comments for Other OGD Disciplines

Discipline	Comment
None	

6 APPENDIX

6.1 Individual Study Reviews

6.1.1 Fasting Bioequivalence Study

6.1.1.1 Study Design

Table 4 Study Information

Study Number	80018
Study Title	Randomized, Open-Label, 2-Way Crossover, Bioequivalence Study of Atorvastatin 80 mg Tablet and Lipitor® (Reference) Following a 80 mg Dose in Healthy Subjects Under Fasting Conditions
Clinical Site (Name & Address)	Anapharm 4101 Yonge Street, Suite 600 P.O. BOX 222 Toronto (Ontario), Canada M2P 1N6 Tel.: (416) 227-1512 Fax: (416) 227-1502
Principal Investigator	Shafik Dharamshi, M.D.
Dosing Dates	Group 1: Subjects No. 01-03, 05-17, 20-38, and 40 2008-04-04 and 2008-04-18 Group 2: Subjects No. 04, 18, 19, 39, and 41-80 2008-04-13 and 2008-04-27
Analytical Site (Name & Address)	(b) (4)
Analysis Dates	
Analytical Director	
Storage Period of Biostudy Samples (no. of days from the first day of sample collection to the last day of sample analysis)	91 days (2008-04-04 to 2008-07-04)

Table 5. Product information

Product	Test	Reference
Treatment ID	A	B
Product Name	Atorvastatin calcium Film-Coated Tablets	Atorvastatin calcium (Lipitor®)
Manufacturer	*Sandoz Inc.	Pfizer Ireland Pharmaceuticals, Ireland for Pfizer Inc., USA
Batch/Lot No.	30004016	15267V
Manufacture Date	February, 2008	
Expiration Date		September, 2010
Strength	80 mg	80 mg
Dosage Form	film-coated tablet	film-coated tablet
Bio-Batch Size	(b) (4)	
Production Batch Size		
Potency (Assay)	(b) (4)	(b) (4)
Content Uniformity (mean, %CV)	101.3% (mean), 2.4 (AV)	
***Dose Administered**	1 x 80 mg	1 x 80 mg
Route of Administration	Oral	Oral

*The previous ANDA holder, Lek Pharmaceuticals d.d., transferred its business activity to Sandoz Inc. on January 1, 2008.

Table 6. Study Design, Steady State Bioequivalence Study

Number of Subjects	80 enrolled, 80 dosed and 72 completed
No. of Sequences	2
No. of Periods	2
No. of Treatments	2
No. of Groups	2
Washout Period	14 days
Randomization Scheme	AB: 02, 03, 06, 07, 11,12, 15, 16, 17, 18, 21, 23, 25, 27, 30, 31, 35, 36, 37, 39, 42, 44, 45, 48, 51, 52, 53, 56, 59, 60, 61, 64, 65, 67, 69, 71, 74, 75, 77, 80 BA: 01, 04, 05, 08, 09, 10, 13, 14, 19, 20, 22, 24, 26, 28, 29, 30, 32, 33, 34, 38, 40, 41, 43, 46, 47, 49, 50, 54, 55, 57, 58, 62, 63, 66, 68, 70, 72, 73, 76, 78, 79
Blood Sampling Times	Predose and 0.167, 0.333, 0.500, 0.750, 1.00, 1.33, 1.67, 2.00, 2.50, 3.00, 3.50, 4.00, 4.50, 5.00, 6.00, 7.00, 8.00, 10.00, 12.00, 16.00, 20.0, 24.00, 30.0, 36.0, 48.0 (±0.5), and 60.0 (±0.5) hours post-dose in each period.
Blood Volume Collected/Sample	4 ml
Blood Sample Processing/Storage	All blood samples were drawn into blood collection tubes (1 x 4 mL) containing the anti-coagulant, EDTA K_3, prior to drug administration. Blood samples were cooled in an ice bath and were centrifuged at 3,000 rpm for at least 10 minutes at approximately 4°C. Two aliquots of at least 0.7 mL (when possible) of plasma were dispensed into polypropylene tubes (as soon as possible), containing a sodium phosphate stabilization solution (1 M, pH 6.00), resulting in a plasma: buffer ratio of 20:1 and were vortexed approximately 10 seconds. The aliquots were flash-frozen at approximately -80°C and subsequently transferred to a -80°C (-65°C to -90°C) freezer, pending shipment to the analytical facility. No more than 110 minutes passed between the time of each blood draw and the start of centrifugation and no more than 180 minutes passed between the start of centrifugation and aliquot storage.
IRB Approval	Yes (2/26/2008)
Informed Consent	Yes
Length of Fasting	All the subjects fasted for at least 10 hours prior to the administration of the study drug in each period until 4 hours postdose.
Length of Confinement	At least 10 hours prior to drug administration until after the 36.0-hour post-dose blood draw, in each period.
Safety Monitoring	Adverse events were collected and reports were tabulated. Physical examinations, vital signs measurements and electrocardiograms were performed at the time of screening and on the last study day. Hematology and Biochemistry (ALT, AST, alkaline phosphatase, Urea, Calcium, chloride, Glucose, Phosphorus, Potassium, Serum creatinine, sodium, Total bilirubin, Total protein, GGT, CPK, Direct bilirubin) investigations were done at the time of screening and on the last study day. The study physician was on site for dosing and for at least 6 hours thereafter and on call for the duration of the study.

Comments on Study Design:

The study design is acceptable.

6.1.1.2 Clinical Results

Table 7. Demographics Profile of Subjects Completing the Bioequivalence Study

Steady State Bioequivalence Study No. 80018			
		Treatment Groups	
		Test Product N = 72	Reference Product N = 72
Age (years)	Mean ± SD	35 ± 9	35 ± 9
	Range	18 - 54	18 - 54
Age Groups	< 18	0 (0.00%)	0 (0.00%)
	18 – 39	50 (69.4 %)	50 (69.4 %)
	40 – 64	22 (30.6 %)	22 (30.6 %)
	65 – 75	0 (0.00%)	0 (0.00%)
	> 75	0 (0.00%)	0 (0.00%)
Sex	Male	70 (97.2 %)	70 (97.2 %)
	Female	2 (2.8 %)	2 (2.8 %)
Race	Asian	8 (11.1 %)	8 (11.1 %)
	Black	14 (19.4 %)	14 (19.4 %)
	White	39 (54.2 %)	39 (54.2 %)
	Other	11 (15.3 %)	11 (15.3 %)
Ethnicity	Not Hispanic	56 (77.8 %)	56 (77.8 %)
	Hispanic	16 (22.2 %)	16 (22.2 %)
BMI	Mean + SD	25.3 ± 2.1	25.3 ± 2.1
	Range	19.6 - 27.9	19.6 - 27.9
Height	Mean + SD	174.7 ± 6.7	174.7 ± 6.7
	Range	161.5 - 188.5	161.5 - 188.5
Weight	Mean ± SD	77.4 ± 9.0	77.4 ± 9.0
	Range	54.4 - 96.7	54.4 - 96.7

Table 8. Dropout Information, Fasting Bioequivalence Study

Study No. 80018				
Subject No	**Reason for dropout/replacement***	**Period**	**Replaced?**	**Replaced with**
24	2008-04-17 16:00 / reference / elected to withdraw (subject did not show up for Period 2 confinement)	Period 1	No	Not applicable
47	2008-04-26 18:00 / reference / elected to withdraw (subject did not show up for Period 2 confinement)	Period 1	No	Not applicable
49	2008-04-26 18:00 / reference / elected to withdraw (subject did not show up for Period 2 confinement)	Period 1	No	Not applicable
52	2008-04-26 15:10 / test / elected to withdraw due to personal reasons (subject did not show up for Period 2 confinement)	Period 1	No	Not applicable
53	2008-04-27 07:19 / test / was withdrawn due to positive urine cotinine test	Period 1	No	Not applicable
59	2008-04-16 15:08 / test / was withdrawn as per Sponsor request because subject had an eye infection that required treatment with antibiotics	Period 1	No	Not applicable
64	2008-04-26 18:00 / test / elected to withdraw (subject did not show up for Period 2 confinement)	Period 1	No	Not applicable
77	2008-04-26 16:11 / test / was withdrawn because subject was found with an Informed Consent Form from another CRO during check-in of Period 2	Period 1	No	Not applicable

Table 9. Study Adverse Events, Fasting Bioequivalence Study

Body System / Adverse Event	**Reported Incidence by Treatment Groups**	
	Study No 80018	
	Test (N = 77)	**Reference (N = 75)**
	N (%)	**N (%)**
Body as a whole	**2 (2.6%)**	**4 (5.3%)**
Headache	2 (2.6%)	2 (2.7%)
Pain		1 (1.3%)
Pain abdominal		1 (1.3%)
Cardiovascular system		**1 (1.3%)**
Palpitation		1 (1.3%)
Digestive system	**3 (3.9%)**	**1 (1.3%)**

Eructation	1 (1.3%)	
Nausea	2 (2.6%)	1 (1.3%)
Metabolic and Nutritional Disorders	**2 (2.6%)**	**3 (4.0%)**
Creatinine PK increase	2 (2.6%)	2 (2.7%)
Edema peripheral		1 (1.3%)
Musculoskeletal System	**1 (1.3%)**	**1 (1.3%)**
Myalgia	1 (1.3%)	1 (1.3%)
Central Nervous System	**8 (10.4%)**	**7 (9.3%)**
Dizziness	1 (1.3%)	
Somnolence	8 (10.4%)	7 (9.3%)
Skin and Appendages	**1 (1.3%)**	
Nail disorder	1 (1.3%)	
Special Senses	**2 (2.6%)**	**1 (1.3%)**
Conjunctivitis	2 (2.6%)	1 (1.3%)
Dry eye	1 (1.3%)	
Total	**21 (18.2%)**	**17 (18.7%)**

Table 10. Protocol Deviations, Fasting Bioequivalence Study

Study No. 80018		
Type	**Subject #s (Test)**	**Subject #s (Ref.)**
In Period 1, the Medical Sub-Investigator remained on site for as little as 5 hours and 51 minutes after study drug administration to the last subject from Group 1, instead of 6 hours as required by protocol. However, a Medical Sub-Investigator was on call for the remainder of the study, and subject safety was not jeopardized.	02, 03, 06, 07, 11, 12, 15-17, 21, 23, 25, 27, 30, 31, 35, 36, and 37	01, 05, 08-10, 13, 14, 20, 22, 24, 26, 28, 29, and 32-34
Sample processing times were not respected in Period 2 Group 2 for the 2.00 hour post-dose blood draw. Blood samples were not stored within the time limits based on the AMIS requirements for storage to be completed within 180 minutes from start of centrifugation until time of storage; the maximum delay was 50 minutes. There was no impact since all analytes were found to be stable in EDTA K_2 for at least 9 hours.	04, 19, 41, 43, 46, 50, 54, 55, 57, 58, 62, 63, 66, 68, 70, 72, 73, 76, 78, and 79	18, 39, 42, 44, 45, 48, 51, 56, 60, 61, 65, 67, 69, 71, 74, 75, and 80

The urine cotinine test was not performed at screening for this subject due to technical oversight. However, this test was done at check-in of Period 1 and the result was negative.		58 (pre-dose)
This subject was enrolled in the study without confirming eligibility. A repeat hemoglobin test was requested due to abnormal test results at screening, but it was not performed prior to check-in, in error. However, subject eligibility would not have been refused since the haemoglobin result was only 1mg/dl lower than the lower limit of the accepted range. Moreover, post-study results indicated that haemoglobin results were not clinically significant.	34	34
No post-study procedures were performed for this subject. The subject could not be contacted to return to the clinical facility for post-study procedures. No adverse events that were consistent with significant safety issues were reported for this subject during the study. A letter was sent referring the subject to his family physician for follow-up		49
Medication dispensing was done more than 24 hours prior to dosing in Period 1and Period 2 for Group 02. The sponsor was contacted regarding this arrangement and did not object.	04, 18, 19, 39, 4, 42-46, 48, 50-52, 54, 55-57, 58-63, 64-69, and 70-80	04, 18, 19, 39, 41-51, 54-58, 60-63, 65-76, and 78-80

Comments on Dropouts/Adverse Events/Protocol Deviations: Acceptable.

- A total of 80 healthy subjects were enrolled and dosed. Eight Subjects (#24, #47, #49, #52, #53, #59, #64 and #77) were dropped out of the study due to failure to report to the study facility in Period 2, positive urine cotinine test (for nicotine tobacco), conflicting consent with another CRO or concurrent illness (eye infection) and 72 subjects completed the study. None of the subjects withdrawn from the fasting study was due to adverse drug event.

- No severe adverse event of the drug occurred.

- The firm's handling of dropouts, adverse events and protocol deviation is acceptable.

- There were some blood sampling deviations during fasting bioequivalence study. However, these sampling time deviations occurred in less than 10% of the nominal time points, thus are considered to be insignificant by the reviewer. The sample time deviations did not compromise the outcome of the BE study. The firm used actual sampling times for its PK calculation.

6.1.1.3 Bioanalytical Results

Table 11A. Assay Validation – Within the Fasting Bioequivalence Study

Bioequivalence Study No. 80018 Atorvastatin								
Parameter	**Standard Curve Samples**							
Concentration (pg/mL)	50.16	100.32	2006.40	5016.00	10032.00	20064.00	40128.00	50160.00
Inter day Precision (%CV)	4.97	4.20	3.38	2.99	3.01	2.75	2.66	2.81
Inter day Accuracy (% deviated)	0.76	-1.56	1.05	1.10	1.19	-0.33	-1.23	-0.96
Linearity (Range of R^2 values)	0.9960 to 0.9996							
Linearity Range (pg/mL)	50.16 to 50160.00							
Sensitivity/LOQ (pg/mL)	50.16							

Bioequivalence Study No. 80018 Atorvastatin				
Parameter	**Quality Control Samples**			
Concentration (pg/mL)	150.48	2508.00	15048.00	35112.00
Inter day Precision (%CV)	5.70	4.04	3.81	4.09
Inter day Accuracy (% deviated)	1.85	1.94	0.50	-1.23

Table 11B. Assay Validation – Within the Fasting Bioequivalence Study

Bioequivalence Study No. 80018 o-Hydroxy-Atorvastatin								
Parameter	**Standard Curve Samples**							
Concentration (pg/mL)	50.08	100.16	2003.20	5008.00	10016.00	20032.00	40064.00	50080.00
Inter day Precision (%CV)	7.54	5.58	2.54	2.04	2.27	2.51	1.80	2.19
Inter day Accuracy (% deviated)	0.66	-1.31	0.75	-0.30	0.22	-0.36	-0.20	0.63
Linearity (Range of R^2 values)	0.9939 to 0.9998							
Linearity Range (pg/mL)	50.08 to 50080.00							
Sensitivity/LOQ (pg/mL)	50.08							

Bioequivalence Study No. 80018 o-Hydroxy-Atorvastatin				
Parameter	**Quality Control Samples**			
Concentration (pg/mL)	150.24	2504.00	15024.00	35056.00
Inter day Precision (%CV)	7.54	3.56	3.04	3.57

Inter day Accuracy (% deviated)	1.42	1.28	0.48	-0.44

Table 11C. Assay Validation – Within the Fasting Bioequivalence Study

Bioequivalence Study No. 80018 para-Hydroxy-Atorvastatin								
Parameter	**Standard Curve Samples**							
Concentration (pg/mL)	50.40	100.80	201.60	504.00	1008.00	2016.00	4032.00	5040.00
Inter day Precision (%CV)	6.52	5.07	4.66	3.60	2.95	2.90	2.85	2.70
Inter day Accuracy (% deviated)	0.48	-1.30	0.63	-0.13	0.01	-0.24	-0.27	0.72
Linearity (Range of R^2 values)	0.9931 to 0.9996							
Linearity Range (pg/mL)	50.40 to 5040.00							
Sensitivity/LOQ (pg/mL)	50.40							

Bioequivalence Study No. 80018 para-Hydroxy-Atorvastatin				
Parameter	**Quality Control Samples**			
Concentration (pg/mL)	151.20	252.00	1512.00	3528.00
Inter day Precision (%CV)	6.83	5.64	3.29	3.18
Inter day Accuracy (% deviated)	-1.12	0.71	-0.57	-1.58

Comments on Study Assay Validation:

Acceptable.

Any interfering peaks in chromatograms?	No
Were 20% of chromatograms included?	Yes
Were chromatograms serially or randomly selected?	Serially selected (from Subj#1 to Subj#16)

Comments on Chromatograms:

Acceptable.

Table 12. SOP's Dealing with Bioanalytical Repeats of Study Samples

SOP No.	**Effective Date of SOP**	**SOP Title**
ANI 156.09	2005-09-23	Sample Reassays and Reporting of Final Concentrations

Table 13. Additional Comments on Repeat Assays

Were all SOPs followed?	The analytical raw numerical data for all sample reassays were not submitted. The reviewer comment(s) regarding the reassay samples will be provided after the firm responds the deficiency comments
Did recalculation of PK parameters change the study outcome?	The reassays coded as "Sample reanalyzed to obtain confirming value" is considered as a PK repeat. The reviewer will re-evaluate the fasting study after receiving a complete set of the firm's reassay data
Does the reviewer agree with the outcome of the repeat assays?	Please see the above comments
If no, reason for disagreement	

Summary/Conclusions, Study Assays:

Incomplete. The firm did not submit complete raw numerical data for all study sample reassays.

6.1.1.4 Pharmacokinetic Results

Please note that the information below is obtained based on the assumption that the firm's repeated assays are acceptable, and the reviewer used the firm's repeated assay values for the calculation. The PK parameter calculation results may change upon the DBE's receipt of additional information and re-evaluation of the firm's repeated assays.

Table 14. Arithmetic Mean Pharmacokinetic Parameters

Mean serum concentrations are presented in Table 18 and Figure 1

Fasting Bioequivalence Study, 80018 Analyte: Atorvastatin									
Parameter (units)	**Test**				**Reference**				**T/R**
	Mean	**%CV**	**Min**	**Max**	**Mean**	**% CV**	**Min**	**Max**	
AUC_{0-t} (pg*hr /mL)	162499.7	57.01	56138.47	759160.0	149122.9	40.32	43959.94	453355.0	1.09
AUC∞ (pg*hr /mL)	165065.2	56.30	57345.45	761837.1	153180.2	40.30	45610.79	472881.5	1.08
Cmax (pg /mL)	40041.84	65.16	11142.30	185784.7	40663.51	52.72	4224.78	112175.6	0.98
Tmax (hrs)*	1.67	.	0.50	4.50	0.75	.	0.43	4.50	2.23
Kel (hr-1)	0.06	24.35	0.03	0.10	0.06	29.07	0.02	0.10	1.02
Thalf (hrs)	12.20	27.18	6.71	26.44	12.86	37.30	6.93	37.51	0.95

*Median

Fasting Bioequivalence Study, 80018 Analyte: o-Hydroxy-Atorvastatin									
Parameter (units)	Test				Reference				T/R
	Mean	%CV	Min	Max	Mean	% CV	Min	Max	
AUC_{0-t} (pg*hr /mL)	166063.5	52.06	68077.23	719415.2	161805.0	42.60	45823.22	550392.8	1.03
AUC∞ (pg*hr /mL)	167800.0	51.48	69555.47	725971.3	167235.9	42.86	50420.26	593282.7	1.00
Cmax (pg /mL)	26729.28	53.42	7849.77	101107.1	29400.60	45.14	1549.06	63364.50	0.91
Tmax (hrs) *	1.67	.	0.75	4.50	1.00	.	0.50	16.00	1.67
Kel (hr-1)	0.06	30.61	0.03	0.12	0.06	27.49	0.02	0.11	1.08
Thalf (hrs)	12.43	32.71	5.60	24.48	13.25	32.59	6.52	31.38	0.94

*Median

Fasting Bioequivalence Study, 80018 Analyte: p-Hydroxy-Atorvastatin									
Parameter (units)	Test				Reference				T/R
	Mean	%CV	Min	Max	Mean	% CV	Min	Max	
AUC_{0-t} (pg*hr /mL)	21929.90	76.05	5144.06	121929.0	18647.83	58.26	2925.50	72572.90	1.18
AUC∞ (pg*hr /mL)	25533.87	71.50	6667.71	145131.9	22764.86	54.48	4307.89	90498.21	1.12
Cmax (pg /mL)	1416.24	97.99	318.06	11239.72	1076.73	62.36	206.68	3185.31	1.32
Tmax (hrs) *	4.50	.	0.75	10.00	6.50	.	0.50	60.00	0.69
Kel (hr-1)	0.03	35.76	0.01	0.06	0.03	32.25	0.01	0.05	1.08
Thalf (hrs)	23.00	40.82	11.01	52.32	24.61	41.39	13.01	69.67	0.93

*Median

Table 15. Geometric Means and 90% Confidence Intervals - Firm Calculated

Atorvastatin Calcium Dose (1 x 80 mg) (N=72) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for Atorvastatin				
Fasting Bioequivalence Study, 80018				
Parameter	Test	Reference	Ratio (%)	90% C.I.
AUC_{0-t} (pg*hr /mL)	147342.59	138985.06	106.01%	100.65% to 111.66%
AUC∞ (pg*hr /mL)	149924.21	142963.45	104.87%	100.10% to 109.87%
Cmax (pg /mL)	34499.03	35521.73	97.12%	85.75% to 110.00%

Atorvastatin Calcium Dose (1 x 80 mg) (N=72) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for o-Hydroxy-Atorvastatin				
Fasting Bioequivalence Study, 80018				
Parameter	**Test**	**Reference**	**Ratio (%)**	**90% C.I.**
AUC_{0-t} (pg*hr /mL)	153062.45	150125.76	101.96%	95.20% to 109.19%
AUC∞ (pg*hr /mL)*	155209.33	156541.21	99.15%	93.88% to 104.71%
Cmax (pg /mL)	23976.97	25249.26	94.96%	83.10% to 108.51%

* For this parameter, N=71

Atorvastatin Calcium Dose (1 x 80 mg) (N=72) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for p-Hydroxy-Atorvastatin				
Fasting Bioequivalence Study, 80018				
Parameter	**Test**	**Reference**	**Ratio (%)**	**90% C.I.**
AUC_{0-t} (pg*hr /mL)	18505.50	16167.13	114.46%	106.81% to 122.66%
AUC∞ (pg*hr /mL)*	22120.39	20140.93	109.83%	103.32% to 116.75%
Cmax (pg /mL)	1139.48	901.71	126.37%	113.69% to 140.47%

* For this parameter, N=63

Table 16. Geometric Means and 90% Confidence Intervals - Reviewer Calculated

Atorvastatin Calcium Dose (1 x 80 mg) (N=72) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for Atorvastatin					
Fasting Bioequivalence Study, 80018					
Parameter (units)	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	147342.6	138985.1	1.06	100.65	111.66
AUC∞ (pg*hr /mL)*	149924.2	142963.5	1.05	100.10	109.87
Cmax (pg /mL)	34499.03	35521.73	0.97	85.75	110.00

Atorvastatin Calcium Dose (1 x 80 mg) (N=71) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for o-Hydroxy-Atorvastatin					
Fasting Bioequivalence Study, 80018					
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	153062.4	150125.8	1.02	95.20	109.19
AUC∞ (pg*hr /mL)*	155209.3	156541.2	0.99	93.88	104.71
Cmax (pg /mL)	23976.97	25249.26	0.95	83.10	108.51

Atorvastatin Calcium Dose (1 x 80 mg) (N=63) Least Squares Geometric Means, Ratio of Means, and 90% Confidence Intervals Bioavailability Data for p-Hydroxy-Atorvastatin					
Fasting Bioequivalence Study, 80018					
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**	
AUC_{0-t} (pg*hr /mL)	18505.50	16167.13	1.14	106.81	122.66
AUC∞ (pg*hr /mL)*	22120.39	20140.93	1.10	103.32	116.75
Cmax (pg /mL)	1139.48	901.71	1.26	113.69	140.47

Table 17. Additional Study Information, Fasting Study 80018

For Atorvastatin:

Root mean square error, AUC_{0-t}	0.1862	
Root mean square error, AUC∞	0.1672	
Root mean square error, Cmax	0.4470	
	Test	**Reference**
Kel and AUC∞ determined for how many subjects?	72	72
Do you agree or disagree with firm's decision?	Yes	Yes
Indicate the number of subjects with the following:		
measurable drug concentrations at 0 hr	0	0
first measurable drug concentration as Cmax	0	0
Were the subjects dosed as more than one group?	No	No

Ratio of AUC0-t/AUC∞				
Treatment	**n**	**Mean**	**Minimum**	**Maximum**
Test	72	0.98	0.94	1.00
Reference	72	0.97	0.54	1.00

For o-Hydroxy-Atorvastatin:

Root mean square error, AUC_{0-t}	0.2461	
Root mean square error, AUC∞	0.1943	
Root mean square error, Cmax	0.4789	
	Test	**Reference**
Kel and AUC∞ determined for how many subjects?	71	71
Do you agree or disagree with firm's decision?	Yes	Yes
Indicate the number of subjects with the following:		
measurable drug concentrations at 0 hr	0	0
first measurable drug concentration as Cmax	0	0
Were the subjects dosed as more than one group?	No	No

Ratio of AUC0-t/AUC∞				
Treatment	**n**	**Mean**	**Minimum**	**Maximum**
Test	71	0.98	0.90	1.00
Reference	71	0.98	0.84	1.00

For p-Hydroxy-Atorvastatin:

Root mean square error, AUC_{0-t}	0.2484	
Root mean square error, AUC∞	0.2037	
Root mean square error, Cmax	0.3797	
	Test	**Reference**
Kel and AUC∞ determined for how many subjects?	63	63
Do you agree or disagree with firm's decision?	Yes	Yes
Indicate the number of subjects with the following:		
measurable drug concentrations at 0 hr	0	0
first measurable drug concentration as Cmax	0	0
Were the subjects dosed as more than one group?	No	No

Ratio of AUC0-t/AUC∞				
Treatment	**n**	**Mean**	**Minimum**	**Maximum**
Test	63	0.83	0.54	0.97
Reference	63	0.81	0.46	0.95

Comments on Pharmacokinetic and Statistical Analysis:

- Subjects enrolled in this study were dosed in different days and divided into two groups (Group 1-P1: 04/04/2008 and P2: 04/18/2008 for Subject #s 01-03, 05-17, 20-38, & 40; Group 2- P1: 04/13/2008 and P2: 04/27/2008 for Subject #s 04, 18, 19, 39, & 41-80). The reviewer used the model GRP SEQ SEQ*GRP SUB (SEQ*GRP) PER (GRP) TRT TRT*GRP for statistical analysis. There was no significant TRT*GRP effect (p>0.1) for AUC0-t, AUC∞ and Cmax. Therefore, this term was dropped from subsequent analysis.

- Furthermore, the firm conducted the new fasting BE study in a single clinical center and the subjects were recruited from the same population (healthy volunteers) and were randomized to treatments based on randomization schedule outlined in the study protocol. Therefore, the group effect was not considered as a variable in the statistical analysis, and the data could be treated as if all subjects were dosed together.

- The firm assayed the plasma concentration data for atorvastatin, ortho-hydroxy-atorvastatin, and para-hydroxy-atorvastatin. The firm also provided the plasma

profiles for atorvastatin, ortho-hydroxy-atorvastatin, and para-hydroxy-atorvastatin.

- The 90% CIs of LnAUCt, LnAUC∞ and LnCmax for the respective atorvastatin and ortho-hydroxy-atorvastatin calculated by the reviewer agree with the firm's calculation and are within 80% - 125% criteria for BE.

- However, the point estimate for para-hydroxy-atorvastatin did not meet the point estimate of 0.80-1.25 for C_{max}. It was noted that there was high intra-subject variability of the drug product for C_{max} (atorvastatin: 44.70%, ortho-hydroxy-atorvastatin: 47.89%, and para-hydroxy-atorvastatin: 37.97%), and low plasma levels of the para-hydroxy-atorvastatin as compared to the atorvastatin and ortho-hydroxy-atorvastatin. Therefore, the reviewer considers that the bioequivalence determination be based on the 90% CIs data of AUC_{0-t}, AUC_{∞} and C_{max} for atorvastatin, and comparable pharmacokinetic (PK) parameter results for the active metabolites.

- It was noted that there was only one subject (Subject #67) for the reference product in atorvastatin assay, and two subjects (Subject #1 and #73) for the respective test and reference product in para-hydroxy-atorvastatin assay, whose AUCt/AUC∞ ratios were much lower than 0.8 and who had very flat elimination phases (the last 3 to 6 concentration time points reached zero). Since the sampling times for these subjects are adequate, thus they were included in the final statistical analysis by the reviewer.

- Data from reviewer's calculation was generated using SAS code "continu".

- It was also noted that the median Tmax of atorvastatin of the test product (1.67 hrs; range: 0.5-4.50 hrs) is significantly different than that of the reference product (0.75 hrs; range: 0.43-4.50 hrs). Since the half life for atorvastatin is around 14 hours, therefore the onset of the peak drug concentration is less clinically meaningful under chronic dosing and steady-state conditions.

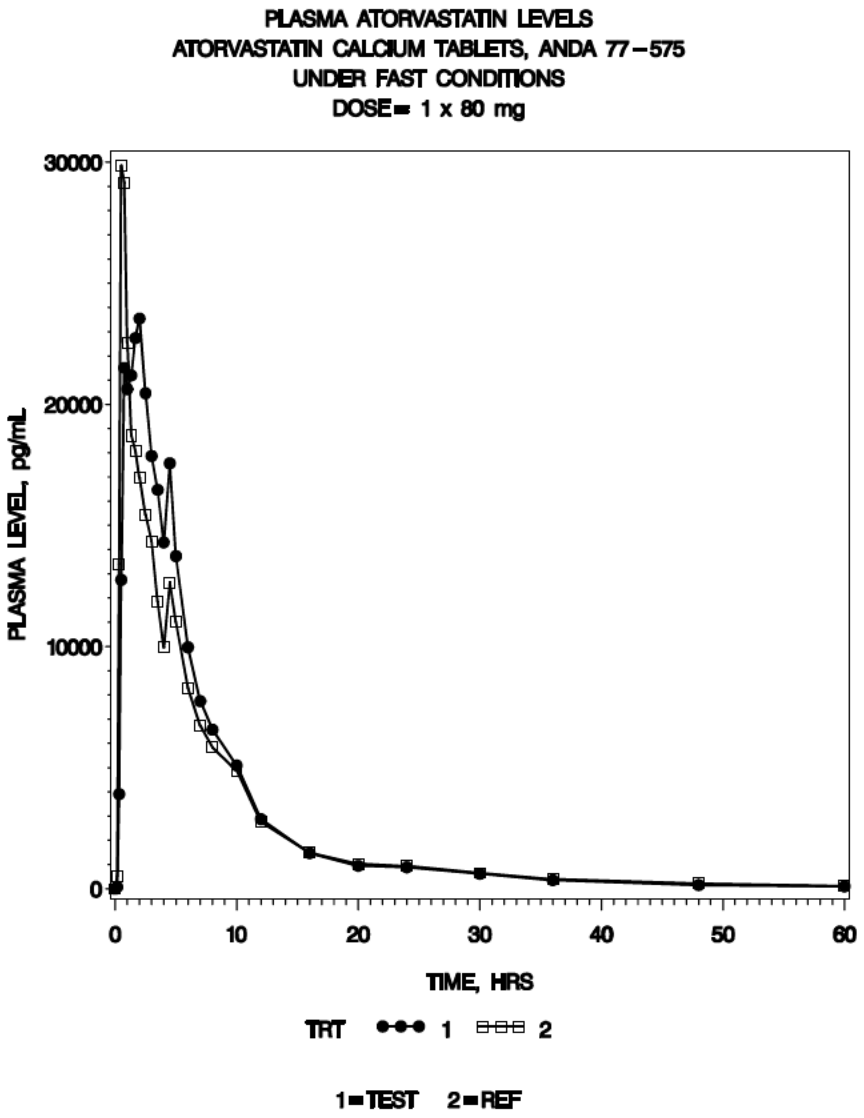
Summary and Conclusions, Single-Dose Fasting Bioequivalence Study:

The firm's in vivo BE study under fasting condition is **inadequate** due to the deficiency listed in Section 5.10 (Deficiency Comments).

Table 18A. Mean Plasma Atorvastatin Concentrations, Fasting Bioequivalence Study

Atorvastatin					
Time (hr)	Test (n= 72)		Reference (n= 72)		T/R Ratio
	Mean (pg/mL)	% CV	Mean (pg/mL)	% CV	
0.00	0.00	.	0.00	.	.
0.17	72.81	304.58	516.23	218.99	0.14
0.33	3909.63	211.82	13412.85	115.52	0.29
0.50	12755.10	195.76	29851.09	78.31	0.43
0.75	21508.56	122.57	29160.92	65.07	0.74
1.00	20629.18	100.07	22541.25	57.30	0.92
1.33	21196.47	94.41	18706.47	57.50	1.13
1.67	22736.88	92.37	18066.96	63.39	1.26
2.00	23542.38	97.95	16974.74	65.92	1.39
2.50	20460.59	106.21	15441.16	60.14	1.33
3.00	17866.80	86.21	14342.03	71.15	1.25
3.50	16472.39	77.59	11850.23	54.56	1.39
4.00	14299.06	75.11	9968.33	53.73	1.43
4.50	17567.23	72.91	12654.39	49.64	1.39
5.00	13734.52	59.33	11013.18	46.32	1.25
6.00	9971.15	59.71	8289.17	45.96	1.20
7.00	7747.88	58.93	6727.54	47.74	1.15
8.00	6569.14	54.68	5833.49	50.54	1.13
10.00	5092.60	47.18	4875.64	44.39	1.04
12.00	2873.17	56.22	2752.97	49.92	1.04
16.00	1471.19	61.25	1485.32	51.33	0.99
20.00	948.28	61.46	1028.78	56.77	0.92
24.00	885.74	71.90	940.42	55.97	0.94
30.00	618.23	57.47	654.53	59.61	0.94
36.00	357.41	63.15	397.48	79.02	0.90
48.00	156.67	72.89	215.66	110.27	0.73
60.00	103.43	89.46	115.58	106.30	0.89

Figure 1A. Mean Plasma Concentrations, Fasting Bioequivalence Study



Reviewer's Comments: It is noticed that the concentration profiles of atorvastatin for the test and reference product showed two peaks. However, the original RLD did not appear to show the same concentration profile characteristics (Enterprise Research: http://fdaesearch.fda.gov:81/SecureES/loadNativeDocument.do?theId=16809223&theLib=bph_lib#xml=http://fdaesearch.fda.gov:81/SecureES/loadPdfDocument.do?theId=16809223&theLib=bph_lib). Per the drug product labeling, atorvastatin does not appear to undergo entrohepatic recirculation (see PK/PD Information section). The reviewer also noticed that concentration profiles in other ANDAs under review (ANDAs 78733 & 90548) for the same drug product show the same profile characteristics as that of the current application (e.g., double peaks).

Table 18B. Mean Plasma o-Hydroxy-Atorvastatin Concentrations, Fasting Bioequivalence Study

o-Hydroxy-Atorvastatin					
Time (hr)	Test (n= 72)		Reference (n= 72)		T/R Ratio
	Mean (pg/mL)	% CV	Mean (pg/mL)	% CV	
0.00	0.00	.	0.00	.	.
0.17	0.00	.	20.44	415.84	0.00
0.33	664.90	269.40	3218.32	151.89	0.21
0.50	3562.28	178.73	12395.95	97.12	0.29
0.75	10331.02	120.47	21594.50	65.77	0.48
1.00	13899.37	98.10	20913.78	56.69	0.66
1.33	16069.42	81.03	19528.10	55.41	0.82
1.67	17374.63	68.36	19156.60	57.38	0.91
2.00	18060.31	69.87	18024.80	57.49	1.00
2.50	18645.57	73.75	17731.96	53.10	1.05
3.00	16596.95	73.69	15802.86	54.52	1.05
3.50	16214.60	72.45	14086.61	50.78	1.15
4.00	15159.19	70.64	12262.88	50.45	1.24
4.50	16498.93	61.48	13297.21	49.00	1.24
5.00	13178.06	58.32	11139.98	47.62	1.18
6.00	10438.04	58.30	8809.03	49.34	1.18
7.00	9243.56	55.98	8123.46	53.34	1.14
8.00	8066.98	52.59	7086.80	50.34	1.14
10.00	6100.78	48.23	5468.19	47.67	1.12
12.00	3797.23	60.56	3423.30	54.29	1.11
16.00	2049.55	59.71	1928.08	52.81	1.06
20.00	1330.39	60.01	1323.14	58.87	1.01
24.00	1247.04	55.25	1181.09	48.24	1.06
30.00	837.66	49.63	839.79	70.64	1.00
36.00	522.74	63.15	541.97	93.16	0.96
48.00	221.51	52.11	280.40	94.21	0.79
60.00	155.08	71.77	172.92	121.55	0.90

Figure 1B. Mean Plasma Concentrations, Fasting Bioequivalence Study

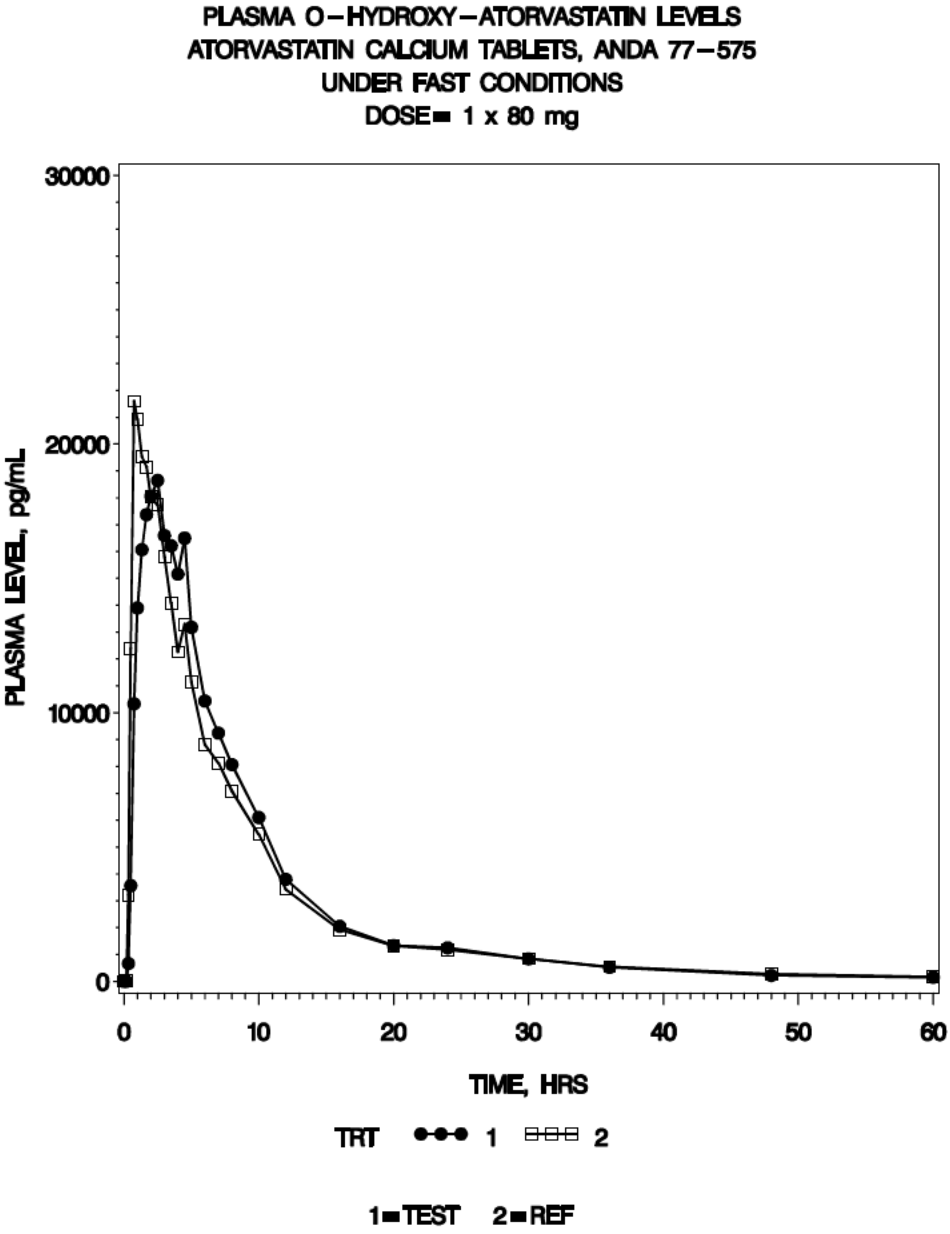
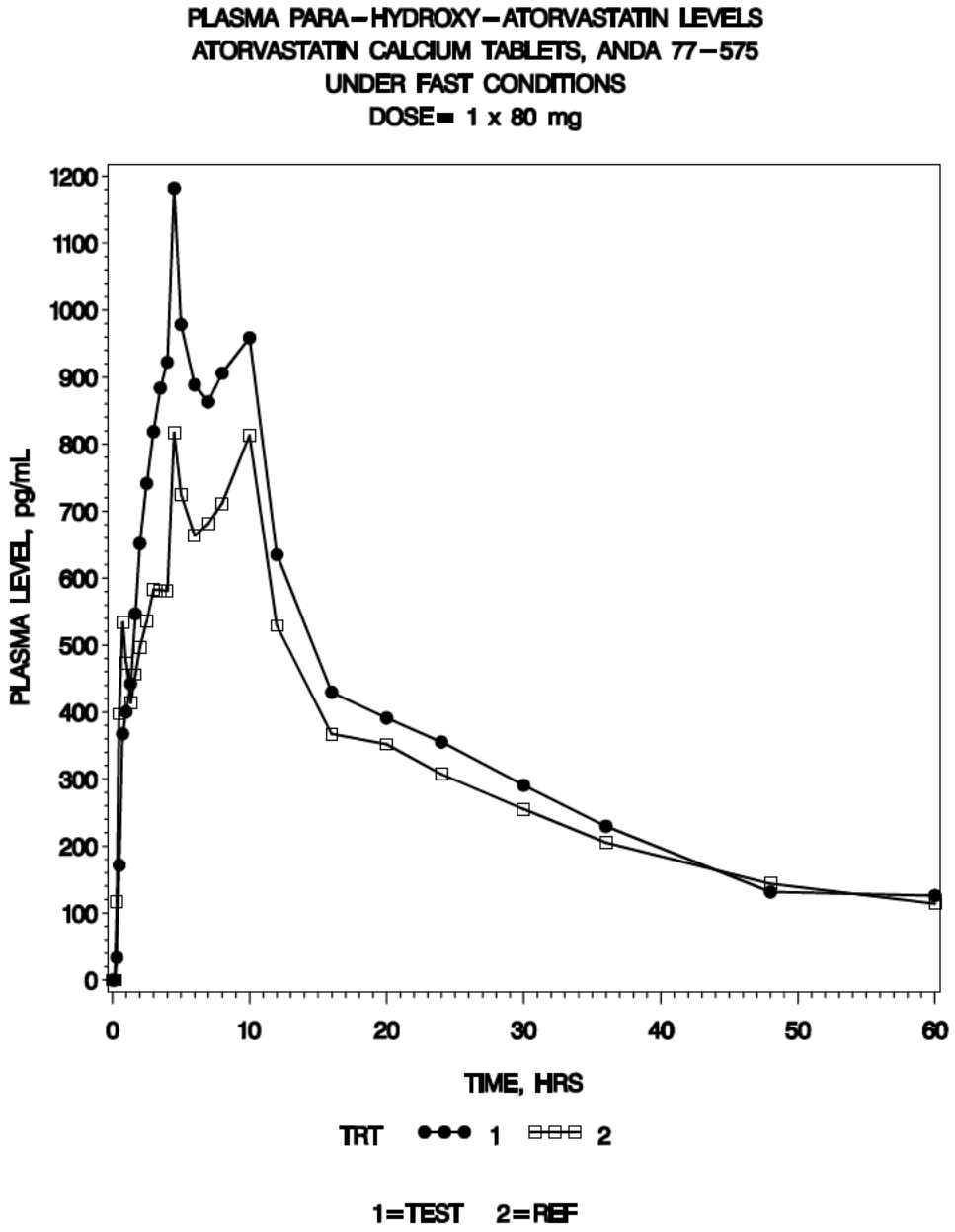


Table 18C. Mean Plasma p-Hydroxy-Atorvastatin Concentrations, Fasting Bioequivalence Study

p-Hydroxy-Atorvastatin					
Time (hr)	Test (n= 72)		Reference (n= 72)		T/R Ratio
	Mean (pg/mL)	% CV	Mean (pg/mL)	% CV	
0.00	0.00	.	0.00	.	.
0.17	0.00	.	0.00	.	.
0.33	33.49	481.19	117.40	184.35	0.29
0.50	171.38	345.81	397.35	129.74	0.43
0.75	367.53	206.17	533.73	99.01	0.69
1.00	400.30	144.06	473.72	86.91	0.85
1.33	442.45	129.22	414.13	81.02	1.07
1.67	546.68	125.94	456.42	83.15	1.20
2.00	651.75	133.04	496.65	84.17	1.31
2.50	741.37	165.90	535.16	78.98	1.39
3.00	818.77	157.94	582.46	74.05	1.41
3.50	883.80	152.55	582.02	70.63	1.52
4.00	922.34	137.65	581.20	70.83	1.59
4.50	1182.20	88.44	817.04	70.19	1.45
5.00	978.64	84.17	724.86	65.50	1.35
6.00	888.63	74.28	663.35	66.29	1.34
7.00	863.18	74.03	681.73	67.80	1.27
8.00	906.00	62.53	711.71	65.68	1.27
10.00	958.74	53.90	812.74	63.81	1.18
12.00	634.95	75.85	528.85	69.79	1.20
16.00	429.64	77.89	367.24	53.26	1.17
20.00	391.20	84.36	351.71	56.81	1.11
24.00	355.41	85.44	307.27	55.77	1.16
30.00	290.76	64.64	255.09	62.34	1.14
36.00	229.67	91.66	205.16	69.70	1.12
48.00	131.48	63.34	143.67	82.98	0.92
60.00	126.05	107.19	114.13	103.12	1.10

Figure 1C. Mean Plasma Concentrations, Fasting Bioequivalence Study



6.2 Formulation Data (Adapted from firm's Formulation Data Table)

Component	Amount (mg)/Tablet				(%) w/w (Tablet (b) (4)			
Strength	**10 mg**	**20 mg**	**40 mg**	**80 mg**	**10 mg**	**20 mg**	**40 mg**	**80 mg**
(b) (4)								
Atorvastatin *	10.000	20.000	40.000	80.000	(b) (4)			
Sodium lauryl sulphate	(b) (4)							
Silicified microcrystalline cellulose								
Pregelatinised starch								
Tromethamine								
Ferric oxide yellow								
Magnesium stearate								
Talc								
Sodium starch glycolate								
Total Tablet (b) (4) ***Wt***								

*The quantity of Atorvastatin is calculated to (b) (4)

(b) (4)

Component	Amount (mg) / Tablet				Amount (%) / Tablet			
Strength	**10 mg**	**20 mg**	**40 mg**	**80 mg**	**10 mg**	**20 mg**	**40 mg**	**80 mg**
Carboxymethylcellulose sodium	(b) (4)							
Glycerin								
Tromethamine								
Sodium lauryl sulphate								
Total Tablet (b) (4) ***Wt***					(b) (4)			

Inactive Ingredients:

Component	†Maximum amount/day based on MDD of Atorvastatin Amount (mg)				Maximum Level Listed in the FDA IIG Database for Approved Drug Products/Unit	Below/Exceed FDA IIG
	10 mg	20 mg	40 mg	80 mg		
Sodium lauryl sulphate	(b) (4)				51.69	Below
Silicified microcrystalline cellulose					1385.3	Below
Pregelatinised starch					435.8	Below
Tromethamine					15.0	Below
Ferric oxide yellow					3.04	Below
Magnesium Stearate, NF					400.74	Below
Talc					220.4	Below
Sodium starch glycolate					876.0	Below
Carboxymethylcellulose sodium					160.0	Below
Glycerin					223.8	Below

†The MDD of Atorvastatin is 80 mg.

Content of Iron in 10 mg (x 8), 20 mg (x 4), 40 mg (x 2) and 80 mg strengths of Atorvastatin Calcium:

Content of Ferric Oxide/80 mg tablet = Ferric Oxide yellow = (b) (4) mg/80 mg of Atorvastatin tablet(s)

Content of elemental iron in Ferric Oxide = (b) (4) %

Therefore, content of elemental iron per 80 mg of Atorvastatin Calcium tablet (MDD) = (b) (4) **< 5 mg**

Is there an overage of the active pharmaceutical ingredient (API)?	N/A
If the answer is yes, has the appropriate chemistry division been notified?	N/A
If it is necessary to reformulate to reduce the overage, will bioequivalence be impacted?	N/A

Comments on the drug product formulation:	1. The amounts of all inactive ingredients in the tablets are below those used in the approved drug products set forth on CDER's Inactive Ingredient Guide (IIG) for Approved Drug Products, on the basis of maximum daily dose of 80 mg of the test product. • The formulations of 10, 20, and 40 mg strength tablets are proportionally similar in their active and inactive ingredients to that of 80 mg strength. • See Reviewer's Additional Comments on Formulation below.

Reviewer's Additional Comments on Formulation:

- Per CFR 21, Part 73, "Listing of Color Additive Exempt From Certification, Subpart B-Drugs", Iron oxide yellow "*may be safety used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day*" (CFR21. 73.1200).

- The maximal daily dose of elemental iron found in 80 mg (MDD) of Atorvastatin Calcium is (b) (4) mg and is less than **5 mg**.

- The formulation is acceptable.

6.3 Dissolution Data

Dissolution Review Path	V:firmsam\lek \ltrs&rev\77575D0205.doc

Table 19A Dissolution Data

Dissolution Conditions	**Apparatus:**	Apparatus 2, USP
	Speed of Rotation:	75 rpm
	Medium:	Potassium phosphate buffer pH 6.8
	Volume:	900 mL
	Temperature:	37 ± 0.5 °C
Firm's Proposed Specifications	Dissolution specification: NLT (b) (4) (Q) dissolved in 15 minutes	
Dissolution Testing Site (Name, Address)	Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana	

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes)**					**Study Report Location**
						5	**10**	**15**	**30**	**45**	
Study Rep. #:	04/10/2007	Test Product ATORVASTATIN CALCIUM Tablets, 10 mg Lot A01179803I	10 mg Tablet	12	Mean	53.9	90.6	93.9	95.9	96.9	Section VI
					Range	(b) (4)					
					%CV	31.5	3.2	1.9	0.8	0.6	
Study Rep. #:	09/24/2004 11/10/2004	Reference Product Lipitor 10 mg tablets Lot 10474V	10 mg Tablet	12	Mean	93.2	97.6	99.0	100.1	100.4	
					Range	(b) (4)					
					%CV	4.4	2.7	2.1	2.2	2.1	

Table 19B Dissolution Data

Dissolution Conditions	**Apparatus:**	Apparatus 2, USP
	Speed of Rotation:	75 rpm
	Medium:	Potassium phosphate buffer pH 6.8
	Volume:	900 mL
	Temperature:	37 ± 0.5 °C
Firm's Proposed Specifications	Dissolution specification: NLT (b) (4) (Q) dissolved in 15 minutes	
Dissolution Testing Site (Name, Address)	Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana	

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes)**					**Study Report Location**
						5	**10**	**15**	**30**	**45**	
Study Rep. #:	04/13/2007	Test Product ATORVASTATIN CALCIUM Tablets, 20 mg Lot A01196903I	20 mg Tablet	12	Mean	27.5	87.7	94.5	96.8	97.4	Section VI
					Range	(b) (4)					
					%CV	48.0	6.0	3.4	2.0	2.0	
Study Rep. #:	11/23/2004	Reference Product Lipitor 20 mg tablets Lot 0483024	20 mg Tablet	12	Mean	94.4	99.2	100.6	101.4	101.3	
					Range	(b) (4)					
					%CV	3.1	1.3	1.3	1.2	1.4	

Table 19C Dissolution Data

Dissolution Conditions	**Apparatus:**	Apparatus 2, USP
	Speed of Rotation:	75 rpm
	Medium:	Potassium phosphate buffer pH 6.8
	Volume:	900 mL
	Temperature:	37 ± 0.5 °C
Firm's Proposed Specifications	Dissolution specification: NLT (b) (4) (Q) dissolved in 15 minutes	
Dissolution Testing Site (Name, Address)	Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana	

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes)**					**Study Report Location**
						5	**10**	**15**	**30**	**45**	
Study Rep. #:	04/12/2007	Test Product ATORVASTATIN CALCIUM Tablets, 40 mg Lot A01198003I	40 mg Tablet	12	Mean	26.4	83.0	92.8	97.3	98.7	Section VI
					(b) (4)						
					%CV	43.6	23.5	7.4	2.4	1.4	
Study Rep. #:	11/15/2004	Reference Product Lipitor 40 mg tablets Lot 0404024	40 mg Tablet	12	Mean	89.9	96.5	99.0	99.6	99.8	
					(b) (4)						
					%CV	3.2	1.7	1.3	1.2	0.9	

Table 19D Dissolution Data

Dissolution Conditions	**Apparatus:**	Apparatus 2, USP
	Speed of Rotation:	75 rpm
	Medium:	Potassium phosphate buffer pH 6.8
	Volume:	900 mL
	Temperature:	37 ± 0.5 °C
Firm's Proposed Specifications	Dissolution specification: NLT (b) (4) (Q) dissolved in 15 minutes	
Dissolution Testing Site (Name, Address)	Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana	

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes)**					**Study Report Location**
						5	**10**	**15**	**30**	**45**	
Study Rep. #:	03/19/2008 03/20/2008	Test Product ATORVASTATIN CALCIUM Tablets, 80 mg Lot 30004016	80 mg Tablet	12	Mean	13.4	69.8	96.0	99.3	100.2	Section VI
					%CV	29.9	6.4	3.3	2.8	2.5	
Study Rep. #:	03/19/2008 03/20/2008	Reference Product Lipitor 80 mg tablets Lot 15267V	80 mg Tablet	12	Mean	83.6	96.0	98.3	100.4	100.8	
					%CV	1.9	1.0	1.3	0.8	1.0	

(b) (4)

Reviewer's Comments on Dissolution Testing:

- The firm's dissolution testing data with the FDA-recommended method are acceptable for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. The test product of these strengths meets the data driven FDA-recommended specification of NLT (b) (4) (Q) in 15 min at the S1 level. However, for the 40 mg (Lot # A01198003I) strength test product, one tablet had unusually low dissolution at 5, 10 and 15 min which resulted in very high CV% at these sampling time points (see firm's dissolution table with the data of 12 individual units below for details). In addition, the 40 mg test product does not meet the specification of NLT (b) (4) (Q) in 15 min. To confirm firm's data, the firm is advised to repeat the dissolution testing

using the FDA-recommended method for the 40 mg strength only. The DBE will set the specification for the test product after reviewing the additional dissolution data.

- The reviewer noted that the firm perform dissolution testing on the lower strengths (e.g. 10 mg, 20 mg and 40 mg strengths) of new batches of the test product (Lot Nos: A01179803I, A01196903I and A01198003I), however used prior dissolution data from old batches of the respective 10 mg, 20 mg and 40 mg strengths of the reference product (Batch Nos: 10474V, 0483024 and 0404024) to compare with new dissolution testing data of the corresponding test product.

- The dissolution testing is **inadequate.**

Table: Percent dissolved of atorvastatin from Atorvastatin calcium film-coated tablet 40 mg tablets, Lot no. A01198003I in 900 mL phosphate buffer pH 6.8 at 37°C, Apparatus 2, USP, 75 rpm, Q is (b) (4) in 15 minutes

Tablet no.	Percent dissolved in minutes				
	5	10	15	30	45
1	(b) (4)				
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
Mean	26.4	83.0	92.8	97.3	98.7
Range	(b) (4)				
RSD	43.6	23.5	7.4	2.4	1.4

6.4 SAS Output

6.4.1 Fasting Study Data

FASTING CONCENTRATION DATA SET FOR ATORVASTATIN

Obs	SUB	SEQ	PER	TREAT	GRP	c1	c2	c3	c4	c5	c6	c7	c8	c9	c10	c11	c12	c13
1	(b) (4)																	
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		
11																		
12																		
13																		
14																		
15																		
16																		
17																		
18																		
19																		
20																		
21																		
22																		

54 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI) IMMEDIATELY FOLLOWING THIS PAGE

6.5 Attachments

SECTION XI: Manufacturing and processing instructions

SECTION XI: Manufacturing and processing instructions

0 Comparison of the previously submitted and the proposed manufacturing processes

- 0.1 ATORVASTATIN CALCIUM Tablets, 10 mg
- 0.2 ATORVASTATIN CALCIUM Tablets, 20 mg
- 0.3 ATORVASTATIN CALCIUM Tablets, 40 mg
- 0.4 ATORVASTATIN CALCIUM Tablets, 80 mg

1 Description of the manufacturing process

- 1.1 ATORVASTATIN CALCIUM Tablets, 10 mg
- 1.2 ATORVASTATIN CALCIUM Tablets, 20 mg
- 1.3 ATORVASTATIN CALCIUM Tablets, 40 mg
- 1.4 ATORVASTATIN CALCIUM Tablets, 80 mg

2 Blank batch records

- 2.1 ATORVASTATIN CALCIUM Tablets, 10 mg
- 2.2 ATORVASTATIN CALCIUM Tablets, 20 mg
- 2.3 ATORVASTATIN CALCIUM Tablets, 40 mg
- 2.4 ATORVASTATIN CALCIUM Tablets, 80 mg

3 Blank packaging records

3.1 ATORVASTATIN CALCIUM Tablets, 10 mg

- 3.1.1 (b) (4)
- 3.1.2 Packaging in plastic bottles, 30 × 10 mg
- 3.1.3 Packaging in plastic bottles, 90 × 10 mg
- 3.1.4 Packaging in plastic bottles, 1000 × 10 mg
- 3.1.5 Packaging in plastic bottles, 3000 × 10 mg

3.2 ATORVASTATIN CALCIUM Tablets, 20 mg

- 3.2.1 (b) (4)
- 3.2.2 Packaging in plastic bottles, 30 × 20 mg
- 3.3.3 Packaging in plastic bottles, 90 × 20 mg
- 3.3.4 Packaging in plastic bottles, 1000 × 20 mg
- 3.3.5 Packaging in plastic bottles, 3000 × 20 mg

31 PAGES HAVE BEEN WITHHELD IN FULL AS B4 (CCI/TS) IMMEDIATELY FOLLOWING THIS PAGE

BIOEQUIVALENCE DEFICIENCIES

ANDA: 77-575

APPLICANT: Sandoz Inc.

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. For your fasting study (Study No. 80018), you did not submit complete raw numerical data of all study sample assay and reassay runs. The raw data should include the peak area/height for the drug, peak area/height for the internal standard, the ratio of the peak area/height for the drug to the peak area/height for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each assayed and reassayed sample, calibration standard samples, and quality control samples.

2. Your dissolution testing data based on the FDA-recommended dissolution method are adequate only for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. However, for the 40 mg (Lot # A01198003I) strength of the test product, it was observed that one tablet had unusually low dissolution at 5, 10 and 15 min which contributed to very high coefficient of variation (CV%) for the mean dissolution values at these sampling time points. To confirm the reproducibility and accuracy of your dissolution data from the 40 mg strength of the test product, please repeat the dissolution testing using the following FDA-recommended method for the 40 mg strength only. The DBE will set the specification for all strengths of the test product after evaluating the additional dissolution data.

   The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate Buffer, pH 6.8, at 37 ± 0.5 ^{0}C, using USP apparatus II at 75 rpm.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence I
Office of Generic Drugs
Center for Drug Evaluation and Research

6.6 Outcome Page

ANDA: 077575

Productivity:

ID	*Letter Date*	*Productivity Category*	*Sub Category*	*Productivity*	*Subtotal*
9751	3/11/2009	Other	Study Amendment	1	1
9751	3/11/2009	Other	Dissolution Waiver	1	1
9751	3/11/2009	Other	Dissolution Waiver	1	1
9751	3/11/2009	Other	Dissolution Waiver	1	1
				Bean Total:	4

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	LEK PHARMACEUTICALS D D	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LI GONG
12/03/2009

BING V LI
12/04/2009

HOAINHON N CARAMENICO on behalf of DALE P CONNER
12/06/2009

DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No.	77575
Drug Product Name	Atorvastatin Calcium Tablets
Strength(s)	10 mg, 20 mg, 40 mg, 80 mg
Applicant Name	Lek Pharmaceuticals d.d. (a Sandoz Company)
Address	Verovskova 57, 1526 Ljubljana, Slovenia
Applicant's Point of Contact	Carmelle Lucas (US Agent – Director of Regulatory Affairs)
Contact's Telephone Number	(609)-627-8854
Contact's Fax Number	(609)-395-2792
Original Submission Date(s)	02/11/2005
Submission Date(s) of Amendment(s) Under Review	April 3, 2007 (current amendment)
Reviewer	Sikta Pradhan, Ph.D.
OUTCOME DECISION	**INCOMPLETE**

Review of a Study Amendment and an Audit Report

I. Executive Summary

This submission contains the firm's response to DBE's deficiency comments of the study amendment (N077575 N000 AB 06-Mar-2006). The submission also contains an audit report (prepared by (b) (4) on two BE studies (AA05474 and AA05473) conducted and analyzed at (b) (4) ((b) (4) The audit report is acceptable. However, the application is still incomplete since the firm's response on the statistical analysis of the study data is incomplete.

Deficiency Comments from the review of study amendment submitted on 3/6/2006:

1. We have reviewed the SAS codes used in your data analysis. Your statistical model is different from that recommended in the agency's statistical guidance "Statistical Approaches to Establishing Bioequivalence", issued in January 2001 for a replicated crossover study. Based on the agency's analysis, your atorvastatin Cmax in the fasting bioequivalence study AA05474 did not meet BE acceptance criterion of 80-125%. The 90% confidence interval calculated by the agency was 98.5-126.7%.

2. The results of one of the active metabolites, para-hydroxyatorvastatin, did not support that your test product is comparable with the reference product. Please explain why DBE should consider your test product is bioequivalent to the reference product based on these data.

Firm's responses to deficiency #1:

1. An example of program statements that may be used to assess BE in replicated crossover study design using PROC MIXED in SAS® was provided in the Appendix E of the FDA guidance entitled "Statistical Approaches to Establishing Bioequivalence", issued in January 2001.

Since program statements were illustrated as an example, we have performed the following evaluations to assess the robustness of the model in determining bioequivalence in semi-replicated study design (3-period replicated design):

(1) The applicability of the FA0(2) variance-covariance matrix structure with the isolated estimation of the intra-variability components (test and reference intra-variability and switchability intra-variability) was first evaluated as per Appendix E of the guidance, using the Satterthwaite option for the calculation of the degrees of freedom.

(2) The applicability of an approach where the intra-variability estimation and SAS® codes would be consistent with a 2-way crossover design approach was evaluated (with PROC MIXED in SAS®), where only the global intra-variability is estimated.

In the 3-period replicated design, results suggest that there may be a lack of robustness in the intra-variance estimates when the components of the global intra-variability are estimated individually (Item 1). This potential lack of robustness could be related to the partial replication of only one formulation per subject. From a practical point of view, for the current study AA05474, a marked impact on the global intra-variability estimate was observed, where the global intra-CV for Cmax obtained when applying the Appendix E coding (Item 1) was 51.3% (refer to Appendix 1), as opposed to 39.2% (refer to Appendix 2) with the standard 2-way crossover study design coding (Item 2). As a result, the impact of the approach suggested in Appendix E on the global intra-variability estimation appears to be very important and this is why a different BE conclusion was observed between both approaches.

Furthermore, the degrees of freedom for the denominator of the Type 3 test of the formulation effect (which are also used for the calculation of the 90% confidence interval for the ratio of least-squares means), obtained when applying the SAS® codes proposed in Appendix E with FA0(2) variance-covariance matrix structure and the Satterthwaite option (i.e., Item 1), are markedly different than those obtained when using the standard 2-way crossover design codes (i.e., Item 2). This is illustrated below.

When estimating only the global intra-variance (standard 2-way crossover design approach):
Type 3 Tests of Fixed Effect

	Num	Den		
Effect	DF	DF	F Value	Pr > F
form	1	96	2.82	0.0964
per	2	96	1.77	0.1761

sequence	1	48	0.08	0.7789

When using the Satterthwaite option (as per Appendix E)

Type 3 Tests of Fixed Effect

	Num	Den		
Effect	DF	DF	F Value	Pr > F
sequence	1	49	0.08	0.7747
form	1	49.1	2.18	0.1461
Period	2	86.5	1.65	0.1980

Since both the period and the formulation effects are "within" effects, the same degrees of freedom are expected for the denominator of the Type 3 test of those two fixed effects.

In light of the above results, and since Appendix E of the guidance seemed solely as illustration of an example/suggestion of SAS coding, it has been preferred to use the same approach with regards to the intra-variability estimation and SAS® codes for a 2-way crossover design. In order not to bias the study results, this choice was made *a priori,* before the conduct of the study, and clearly mentioned in the protocol section 10.2.4 The main results for Cmax are presented below (refer to Appendix 2):

90% Confidence Interval – LCmax

Ratio (A/B)	Lower Limit	Upper Limit	Standard Error
111.656	100.118	124.523	0.06567

In order to demonstrate the robustness of the conclusion of the AA05474 study, an additional statistical analysis was performed on atorvastatin natural log Cmax, by removing the third period entirely (see Appendix 3). This analysis mimicked a two-way crossover study design with sequences AB and BA. This analysis was performed using the SAS® GLM procedure. This additional analysis supported the conclusion of bioequivalence for Cmax.

90% Confidence Interval – LCmax (First Two Periods Only)

Ratio (A/B)	Lower Limit	Upper Limit	Standard Error
107.185	93.0544	123.461	0.084253

It should be noted that the first two periods were also analyzed using PROC MIXED in SAS®, where subject 22 was kept into the statistical analysis even though incomplete (missing at period 2, formulation B). Here again, the main conclusion on bioequivalence on Cmax was maintained.

90% Confidence Interval – LCmax

Ratio (A/B)	Lower Limit	Upper Limit	Standard Error
108.146	93.8928	124.562	0.08423

In conclusion, an example of SAS® program statements that may be used to assess BE in replicated crossover studies was illustrated in FDA guidance. We have performed some tests prior to running the clinical conduct of the study in order to assess the robustness of the program. Results suggest that there may be lack of robustness in the calculation of the global intra-variance estimate when the components of the global intra-variability are estimated individually (test and reference intra-subject variance estimates and switchability variance estimate) and in the calculation of the degrees of freedom used to calculate the 90% confidence intervals. Therefore, the same approach with regards to the intra-variability estimation and SAS® codes as for a 2-way crossover design has been identified *a priori* as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the Protocol. This approach, as well as the analyses based only on the first two periods, resulting to a standard 2-way crossover BE assessment, are all in agreement and support the main conclusion of bioequivalence between the Lek Pharmaceuticals d.d and Parke-Davis (Lipitor®) 80 mg atorvastatin tablets.

Reviewer's comment #1:

Note: This is based on a consultation with FDA statisticians.

A program that may be used to assess BE in a replicated crossover study design was provided in Appendix E of the FDA guidance entitled "Statistical Approaches to Establishing Bioequivalence", issued in January 2001. Here, the sponsor's study uses a two-treatment, three-period replicated crossover design.



This model assumes that the subject means come from a distribution with population mean μ_T and μ_R, and between-subject variances σ_{BT}^2 and σ_{BR}^2. The model allows us to estimate a correlation, ρ (0.7115), between μ_{Tj} and μ_{Rj} and the subject-by-formulation interaction variance σ_D^2(0.1379).

In the sponsor's response, they propose an approach using SAS proc mixed, using the same program statements that would be used to analyze a standard two-treatment, two-period ("two-way") non-replicated crossover design for the analysis of the variable Lcmax (log of Cmax).

(b) (4)

The sponsor applies this approach both to the full dataset and to data from the first two periods only.

The results using different mixed models and datasets are summarized in the table below.

Dataset	Model	Ratio (A/B)	Lower bound	Upper bound	Std error	DF
All	**guidance**	**111.730**	**98.513**	**126.720**	**0.07509**	**49.1**
	sponsor	111.656	100.118	124.523	0.06567	96
Per (1, 2)*	sponsor	108.146	93.8928	124.562	0.08423	47
Per (1, 3)#	sponsor	115.307	100.625	***132.131***	0.08120	48

*: The data from the third period was deleted.
#: The data from the second period was deleted.

The sponsor provided the results for all data and for the dataset 'Per(1, 2)' by using the sponsor's mixed model. We, FDA statistical reviewers, added the results for the dataset 'Per(1, 3)' by using the sponsor's mixed model. The sponsor did not report results for the 'Per(1, 3)' dataset.

The study was two sequences, three periods, two treatments replicated crossover design. The guidance crossover analysis could be used to allow estimation of within-subject variance for the Test and Reference measures and the subject-by-formulation interaction variance component. The sponsor's crossover analysis excluded the possibility of subject-by-formulation interaction and was not suitable for this replicated crossover study.

To see the importance of subject-by-formulation interaction for this data, we may modify the sponsor's proc mixed statements (using SAS version 9.1) to include this term. If we analyze the full dataset (all three periods) using

(b) (4)

(b) (4)

then proc mixed uses the default fitting method, REML (which is variously called *restricted* maximum likelihood or *residual* maximum likelihood.) With these statements the subject-by-formulation interaction variance component is found to be statistically significant (p-value=0.0161) and the 90% confidence interval for μ_T/μ_R is (98.47%, 126.70%.) Alternatively, if we use



then proc mixed uses the Analysis of Variance (ANOVA) fitting method. With these statements the subject-by-formulation interaction variance component is still found to be statistically significant (p-value=0.0053) and the 90% confidence interval for μ_T/μ_R is (98.23%, 127.00%.) In both cases, it is clear that regardless of the fitting method (REML or ANOVA), subject-by-formulation interaction shouldn't be excluded from the model. It is also clear that the 90% confidence intervals are similar to the interval obtained using the guidance approach (which also allows for the possibility of subject-by-formulation interaction) and do not fall within [80%, 125%]. Because proc mixed statements appropriate to the analysis of a non-replicated crossover study were used by the sponsor to analyze a replicated crossover study, the resulting 90% confidence intervals were computed using the wrong error term.

The sponsor, in the response to the FDA deficiency letter, states (on page 3 of 43) "Therefore, the same approach with regards to the intra-variability estimation and SAS® codes as for a 2-way crossover design has been identified *a priori* as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the Protocol." We do not accept that if an unsuitable statistical analysis method is mentioned in the protocol, the agency is bound to accept the results of this unsuitable analysis.

Using dataset 'Per(1, 2)' is not an acceptable scenario due to artificially deleting the measures from the third period with no scientific reason. In addition, if using dataset 'Per(1, 2)' is to be considered, then dataset 'Per(1, 3) should be checked too. The upper bound of the 90% confidence interval for dataset P(1, 3) is 132.131% and is greater than the 125% bioequivalence limit.

Based upon our statistical judgment, the 90% confidence interval, 98.5%-126.7% for the Cmax parameter is deemed the most reasonable result for this study.

Therefore, the firm's fasted study remains incomplete.

2. **Firm's response to deficiency #2**:

It is our understanding that the FDA Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations (March 2003) states that for BE studies, measurement of the parent drug, rather than the metabolite, is recommended, but measurement of metabolites may be preferred when parent drug levels are too low to allow reliable analytical measurement for an adequate length of time (which is not the case for atorvastatin), or if metabolites are formed as a result of presystemic metabolism and contribute meaningfully to safety and/or efficacy.

Atorvastatin is metabolized extensively in the gut wall and liver to two active metabolites (i.e., ortho-hydroxyatorvastatin and para-hydroxyatorvastatin), both of which are equipotent at inhibiting HMG-CoA reductase activity in vitro. However, para-hydroxyatorvastatin probably does not contribute significantly to HMG-CoA reductase inhibitory activity since it is present in much lower concentrations than atorvastatin and ortho-hydroxyatorvastatin. In such a case, the guidance states that the metabolite does not need to be measured. Furthermore, it is also our understanding that whether or not the metabolite contributes meaningfully to efficacy, the guidance recommends that only the parent drug be analyzed using a confidence interval approach, and the metabolite data can be used to provide supportive evidence of comparable therapeutic outcome. Therefore as per the guidance, and as we stated in the protocol prior to the start of the study, we presented the results for ortho-hydroxyatorvastatin and para-hydroxyatorvastatin for information purposes only.

In any event, based on our in-house data, we were aware that due to analytical limitations, the plasma concentrations of para-hydroxyatorvastatin measured following an 80 mg dose of atorvastatin would be too low to characterize the pharmacokinetics of this metabolite robustly. Furthermore, it had been previously demonstrated in the literature that plasma concentrations of para-hydroxyatorvastatin are much lower than those of atorvastatin and ortho-hydroxeatorvastatin after a single oral 40 mg dose, and too low for a reliable pharmacokinetic characterization when an assay with a lower limit of quantitation OLLOQ) of 0.5 ng/mL is used (Reference: Kantola T et al, Effect of itraconazole on the pharmacokinetics of atorvastatin. Clin Pharmacol Ther 1998; 64:58-65).

Although in study AA05474, the subjects received an 80 mg dose and a more sensitive assay was used (LLOQ = 0.25 ng/mL), the pharmacokinetics of para-hydroxyatorvastatin still could not be robustly assessed. Indeed, with the noncompartmental approach, the pharmacokinetics of a drug is considered robust when there is an optimal rich sampling strategy (with at least 15 data points; 5 in each of the absorption, distribution and elimination phases) and the AUC 0-t accounts for more than 80% of the overall AUCinf, which was not observed for para-hydroxyatorvastatin in the majority of subjects in this study. In addition, the pharmacokinetics of a drug is considered robust when the portion of the AUC0-t that is attributed to the LLOQ is less than 10-20%, and when the LLOQ is no more than 5% of the mean Cmax. In this study, we observed that the LLOQ accounted for greater than 20% of the AUC for para-hydroxyatorvastatin and greater than

5% of the Cmax on average. As a result, we concluded that the pharmacokinetics of para-hydroxyatorvastatin in plasma had not been robustly assessed.

For all the above reasons, the primary bioequivalence assessment was based on the results o the parent drug atorvastatin alone, and not on the results of the metabolites.

Reviewer's comment #2:

The data in the cited CPT article (Table II – the placebo arm (i.e. atorvastatin only) in 10 subjects receiving 40 mg atorvastatin) support the firm's argument on "para-hydroxyatorvastatin probably does not contribute significantly to HMG-CoA reductase inhibitory activity since it is present in much lower concentrations than atorvastatin and ortho-hydroxyatorvastatin." The data in the firm's own fasted study also showed relatively lower concentrations of para-hydroxyatorstatin compared to atorvastatin and ortho-hydroxyatorvastatin. Therefore, the firm's response is considered satisfactory.

However, it should be noted that based on the sensitivity of the assay (0.25 ng/mL) for the study, the majority of the study subjects do have valid and measurable concentrations of para-hydroxyatorvastatin.

Review of an audit report

The firm has previously submitted a single-dose fasted and a single-dose fed bioequivalence (BE) study comparing its test product, Atorvastatin Calcium Tablets, 80 mg, to the RLD product, Lipitor®, 80 mg, from Parke-Davis in the original application, dated 2/11/2005. Additionally, the firm also submitted 3 waiver requests for the 10 mg, 20 mg, 40 mg strengths.

The fasted and fed BE studies and waiver requests were incomplete (N077575 N000 AB 06-Mar- 2006). The dissolution testing using the FDA-recommended method was acceptable. The firm has also acknowledged its acceptance of the FDA-recommended dissolution method and specification for this product on 12/05/05.

In response to the current assay integrity issues raised by the Agency for all bioequivalence studies analyzed by (b) (4) during the time period of (b) (4) and at the advice of the Agency, the firm has submitted an independent audit report of the Bioanalytical portion of (b) (4) studies conducted for Lek Pharmaceuticals, d.d. Entitled:

90200 and ZZ00412 "Validation of a High Performance Liquid Chromatographic Mass Spectrometric Method for the Determination of Atorvastatin, Para-hydroxyatorvastatin and Ortho-hydroxyatorvastatin in Human Plasma (EDTA)"

AA05474 "Comparative, Randomized, Single- dose, Semi-Replicate, 3-Way Crossover Bioavailability Study of Lek Pharmaceuticals, d.d. and Parke-Davis (Lipitor^{R}), 80 mg Atorvastatin Tablets (as Atorvastatin Calcium) in Healthy Adult Volunteers Under Fasting Conditions"

AA05473 "Comparative, Randomized, Single- dose, Semi-Replicate, 3-Way Crossover Bioavailability Study of Lek Pharmaceuticals, d.d. and Parke-Davis (Lipitor^{R}), 80 mg Atorvastatin Tablets (as Atorvastatin Calcium) in Healthy Adult Volunteers Under Fed Conditions"

The audit was performed by (b) (4) and (b) (4) (b) (4) The audit included 100% review of method validation data, 100% of the validation chromatograms and review of study data as well as all related SOPs. The audit report has confirmed the validity and integrity of the analytical study data.

Drug Product Information, PK/PD Information, and Relevant DBE History:

Please see the review of the original submissions
V:\firmsam\Lek\ltrs&rev\77575N0205.doc

Background:

As a result of several comprehensive inspections by the Division of Scientific Investigations (DSI), the Agency has concerns with the validity of studies conducted by (b) (4) at the following sites: (b) (4) (b) (4) and (b) (4) between (b) (4). The Agency has informed sponsors of approved or pending ANDAs which were supported by these studies that the Agency cannot proceed with the applications until the issues raised by the DSI are addressed adequately or resolved. The agency recommends the following three options to address the issue: 1) Repeat the bioequivalence studies. 2) Re-assay the samples at a different bioanalytical facility. For this option, the integrity of the original samples must be demonstrated for the frozen storage period. 3) Commission a scientific audit by a qualified independent expert, who is knowledgeable in the area of bioequivalence studies and bioanalytical data, and selected by the applicant rather than by (b) (4) to verify the results obtained by (b) (4)

Please find more information from the attached letter (the letter was located in http://www.fda.gov/cder/news/pharmaco studies/default.htm)

Letter to sponsor of Pending Abbreviated New Drug Application(s) (ANDAs)

January 10, 2007

Dear ANDA Holder/Applicant:

We are writing to you as the sponsor of pending abbreviated new drug application(s) (ANDAs) supported by bioequivalence studies in which the bioanalytical analysis was conducted by [redacted] at the [redacted] ([redacted]) and [redacted] sites in [redacted]

FDA has conducted several comprehensive inspections of bioequivalence studies conducted by [redacted] since [redacted]. The findings of these inspections raise significant concerns about the validity of the reported results of these analytical studies conducted in support of drug applications for marketing. Our findings from these inspections include, but are not limited to, the following:

- Failure to conduct a systematic and thorough evaluation to identify and correct sources of contamination.
- Failure to investigate anomalous results.
- Lack of assay reproducibility between original and repeat results.
- Assay accuracy not assured under the conditions of sample processing.
- Biased manipulation of study data resulting in the acceptance of failed runs.
- Failure to demonstrate the accuracy of analytical methods with appropriate validation experiments and documentation.

As a result of these findings, [redacted] agreed to conduct an audit of data from all its bioequivalence studies generated from [redacted] However, FDA identified significant deficiencies with the [redacted] audit during its most recent inspection. Thus, serious questions remain about the validity of bioequivalence data generated by [redacted] in studies during this time period that have not been inspected by FDA, including the studies you have submitted in support of your applications. In view of these findings, FDA is informing holders of pending ANDA(s) of these issues and would like to know what steps are being taken by you to assure the accuracy of data submitted in these applications and confirm the validity of [redacted] analytical studies that were conducted from [redacted] and subsequently submitted to the FDA. Accordingly, with respect to these studies submitted in your application(s), we request that you do one of the following, in order of FDA preference:

1. Repeat the bioequivalence studies.
2. Re-assay the samples at a different bioanalytical facility. For this option, the integrity of the original samples must be demonstrated for the frozen storage period.
3. Commission a scientific audit by a qualified independent expert, who is knowledgeable in the area of bioequivalence studies and bioanalytical data, and selected by your company rather than by [redacted] to verify the results obtained by [redacted]

In addition, because one of the agency's significant findings for the inspected [redacted] studies was the presence of anomalous results, we are requesting for all of the above options that the blood/plasma level results obtained in the studies be compared to any published literature or other relevant information that is publicly available. If you are unable to complete one of these options within the recommended six month time frame, please inform us of the reason(s) and your estimated time of completion.

If you choose to conduct an audit, we request that the completed audit reports be maintained at your site. If the audit finds the study acceptable, we request that you submit a certification to your

application that formally attests in writing to the validity of the results obtained by (b) (4) upon which your application relies. If the audit finds the study to be unacceptable, you should either repeat the bioequivalence study and submit the information within 6 months of the completed audit or withdraw the application. Please note that these audits would also be subject to validity assessment by the agency upon submission.
The audit criteria provided below includes, but is not limited to, examples of areas that should be evaluated.

- The audit criteria for reviewing pre-study validation data should address whether accuracy and stability were demonstrated with appropriate validation experiments and documentation, and under the conditions of sample processing used for the analysis of samples from study subjects.

- The audit criteria for reviewing the results of the bioequivalence studies should address whether anomalous results were investigated and issues related to contamination were identified and corrected. It should also determine if a comparison of all available original and repeat results demonstrated assay reproducibility, and whether analytical runs were accepted in accordance with established procedures and without bias.

The new bioequivalence data or the re-analysis of the existing data should be submitted to your application as an amendment. If the new information does not support a finding of bioavailability/bioequivalence, the FDA may refuse to approve your application(s). Please find attached the list of your pending applications with studies conducted at (b) (4) during the specified time period.

If you have any questions regarding this letter, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,
/s/ "Gary J. Buehler"
Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Review of the audit report

1. ***The Auditor and Scope of the Audit:***
An independent audit was conducted by (b) (4) on the BE studies (AA05476 and AA05473) analyzed at (b) (4) facility. (b) (4) and (b) (4). performed the review with respect to the findings made by FDA at (b) (4) from (b) (4) to present, and examined the SOPs and all raw data associated with the studies. The method validation and study data were reviewed for accuracy, completeness and adherence to regulatory requirements. Chromatograms acquired during the validation and sample analyses conducted at (b) (4) (b) (4) facility, were reviewed for consistency of integration, interferences, carryover, contamination and any other anomaly that might affect accurate quantitation.

Sample receipt, labeling, storage and use records were also reviewed in depth. The audit report was prepared on March 13, 2007.

2. Audit Findings:

A. Pre-study Method Validation:

The analytical method for atorvastatin and metabolites, para-hydroxy atorvastatin and ortho-hydroxyatorvastatin was validated at the (b) (4) facility of (b) (4) using the stable label (deuterium) compounds, atorvastatin-d_5, para-hydroxyatorvastatin-d_5 and ortho-hydroxyatorvastatin-d_5 as the internal standards. The validation included inter-batch and intra-batch precision and accuracy, specificity, sensitivity, matrix effect, and stability (long term frozen storage, freeze thaw, short term, stock stability).

Sample preparation involved solid Phase extraction followed by LC/MS/MS analysis. Quantitation was by peak area ratio of atorvastatin or its metabolite to internal standard. The validation report is dated August 8, 2001. All validation experiments were analyzed under Project 90107/PPS with exception of long term frozen storage stability (ZZ00412_1/WAU), and stock stability for atorvastatin and ortho-hydroxyatorvastatin (Project 90026/MQT). Revision 1 (dated January 28, 2005) of the report was conducted under Project ZZ00412_01/WAU and incorporated atorvastatin-d_5 with the deuterium in a different position on the molecule which required monitoring at a different mass transition. This Project also contained the long term frozen storage stability for all three analytes at -20^0C and -80^0C, freeze thaw stability at -80^0C and matrix effect.

Comments on Validation

The validation of the assay for ***atorvastatin*** and ***metabolites, para-hydroxy atorvastatin*** and ***ortho-hydroxyatorvastatin*** included inter-batch and intra-batch precision and accuracy, specificity, sensitivity, matrix effect, stability (freeze thaw, short term, stock and re-injection) and dilution integrity.

Atorvastatin

A total of 17 validation runs were conducted and all runs were acceptable (Run 8 PPS was used for ortho-hydroxyatorvastatin only). Five of these runs were test curves for a new preparation of standards and controls. One run (7 PPS) was re-injected for re-injection stability and four runs (5 PPS, 6 PPS, 7 PPS and 12 PPS) were used to assess inter-run precision and accuracy. The remainder of the runs covered a stock solution comparison, a blank matrix check, a spiking solution check, atorvastatin recovery and various stability tests.

A 100% review of all validation raw data was conducted. In addition, 100% of the validation chromatograms were reviewed electronically.

The validation of the assay for atorvastatin displayed acceptable precision and accuracy.
All experiments met the acceptance criteria (mean CV $\leq$ (b)(4)% and accuracy within $\pm$ (b)(4)%).

Review of 100% of the chromatograms from the validation was performed. Each chromatogram was examined for appropriateness of integration as well as consistency in integration between chromatograms. All blank samples (six donors) screened for the validation had interferences less than 20% of the response at the LLOQ. There were no other significant interfering peaks noted in any of the chromatograms at the retention time of the drug or internal standard and integration was appropriate and consistent.

For Project ZZ00412_1/WAU, four runs were attempted. One run was a test curve to validate the vacuum evaporator. Run 2 WAU was a precision and accuracy run conducted to validate the internal standard for atorvastatin. It was acceptable for atorvastatin and para-hydroxyatorvastatin, but ortho-hydroxyatorvastatin did not meet acceptance criteria. Run 3 WAU was a precision and accuracy run for ortho-hydroxyatorvastatin only. Run 4 WAU evaluated matrix effect at the LLOQ and high QC levels, long term frozen storage stability (595 days at -20^{0}C and 64 days at -80^{0}C). All experiments met the acceptance criteria (mean CV $\leq$ (b)(4)% and accuracy within $\pm$ (b)(4)% except at the LLOQ where 20% is acceptable) except as noted.

The assay for atorvastatin was adequately validated and sufficient for producing accurate and reproducible results.

Para-hydroxyatorvastatin

A total of 17 runs were performed and all were acceptable (Run 8 PPS was used for ortho-hydroxyatorvastatin only). Five of these runs were test curves for a new preparation of standards and controls or to validate analysts on the assay. Run7 PPS was re-injected as Run 13 PPS for re-injection stability. Four of the runs (5 PPS, 6 PPs, 7 PPS and 12 ppS) were used to assess inter-run precision and accuracy. The remainder of the runs covered a stock solution comparison, a blank matrix check a spiking solution check, atorvastatin recovery and various stability tests.

A 100% review of all validation raw data was conducted. In addition, 100% of the validation chromatograms were reviewed electronically.

Review of 100% of the chromatograms from the validation was performed. Each chromatogram was examined for appropriateness of integration as well

as consistency in integration between chromatograms. All blank samples (10 donors) screened for the validation had interferences less than 20% of the response at the LLOQ. There were no other significant interfering peaks noted in any of the chromatograms at the retention time of the drug or internal standard and integration was appropriate and consistent.

The validation of the assay for para-hydroxyatorvastatin displayed acceptable precision and accuracy. All experiments met the acceptance criteria (mean CV $\leq$ (b)(4)% and accuracy within $\pm$ (b)(4)%).

The assay for para-hydroxyatorvastatin was adequately validated and sufficient for producing accurate and reproducible results.

Ortho-hydroxyatorvastatin

A total of 17 runs were performed for ortho-hydroxyatorvastatin and all but two runs were acceptable. Run 5 PPS was rejected and the internal standard concentration was lowered for subsequent runs. Run 6PPS was rejected due to low sensitivity and was re-injected as Run 8 PPS. Five of the remaining runs were test curves for a new preparation of standards and controls or to validate analysts on the assay. Run 7PPS was re-injected as Run 13 PPS for re-injection stability. Three of the runs (6PPS, 7PPS and 12PPS)) were used to assess inter-run precision and accuracy. The remainder of the runs covered a stock solution comparison, a blank matrix check a spiking solution check, atorvastatin recovery and various stability tests.

A 100% review of all validation raw data was conducted. In addition, 100% of the validation chromatograms were reviewed electronically.

Review of 100% of the chromatograms from the validation was performed. Each chromatogram was examined for appropriateness of integration as well as consistency in integration between chromatograms. All blank samples (10 donors) screened for the validation had interferences less than 20% of the response at the LLOQ. There were no other significant interfering peaks noted in any of the chromatograms at the retention time of the drug or internal standard and integration was appropriate and consistent.

The validation of the assay for ortho-hydroxyatorvastatin displayed acceptable precision and accuracy. All experiments met the acceptance criteria (mean CV $\leq$ (b)(4)% and accuracy within $\pm$ (b)(4)%).

The assay for ortho-hydroxyatorvastatin was adequately validated and sufficient for producing accurate and reproducible results.

Comments on Study AA05474/WAY

A review of 100% of the raw data associated with study AA05474/WAY was conducted. In addition, 100% of the chromatograms from this study were reviewed electronically.
The 100% chromatograms were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no significant interfering peaks in the chromatograms from this study and integration was consistent and appropriate throughout the study.

Sample receipt and handling were reviewed and it was determined the sample chain of custody was intact. All samples were handled in accordance with method requirements. Also reviewed were the Certificates of Analysis for the reference standard and internal standard (if they were not USP standards), the stock weighings, solution preparation, blank plasma checks and batch extraction records.

This study was conducted between November 16, 2004 and December 21, 2004 under validation 90200/PWB. A total of 65 sample analysis run were performed. The raw data (100%) was reviewed. The analyses for **atorvastatin**, **para-hydroxyatorvastatin** and **ortho-hydroxyatorvastatin** have been discussed below:

Atorvastatin

Runs 1 WAY through 4 WAY, 6 WAY, 13 WAY, and 31 WAY were qualification batches typically for analyst validation and did not contain subject samples. Of the remaining 58 runs, one run was rejected due to an extraction problem and two runs were rejected because the loading of the autosampler could not be verified. Three runs were conducted for the metabolites only. All sample analysis runs attempted for atorvastatin met the acceptance criteria with the exception of the three runs with procedural errors noted above. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no interfering peaks with atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of atorvastatin.

Sixteen samples quantitated above the highest calibration standard and were re-assayed as dilutions. There was excellent agreement (<11% difference) between the original extrapolated value and the reassay (diluted) value. There were two runs repeated for metabolites only. The atorvastatin data was not reported from these runs; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 115 results compared, 114 agreed with a percent difference of <20% and one sample agreed with a percent difference of <30%, thus demonstrating excellent reproducibility. These data are included in Attachment I.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

Parahydroxy Atorvastatin

Runs 1 WAY through 4 WAY, 6 WAY, 13 WAY, and 31 WAY were qualification batches typically for analyst validation and did not contain subject samples. Of the remaining 58 runs, one run was rejected due to an extraction problem and two runs were rejected because the loading of the autosampler could not be verified. One sample analysis run failed due to QCs not meeting acceptance criteria and the remaining 52 sample analysis runs attempted for parahydroxy atorvastatin met the acceptance criteria. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no peaks that interfered with parahydroxy atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of parahydroxy atorvastatin.

The only samples reassayed for parahydroxy atorvastatin were due to extraction errors. There was one run repeated for the orthohydroxy metabolite only. The parahydroxy atorvastatin data was not reported from this run; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 50 results compared, 43 agreed with a percent difference of <20% and 7 samples agreed with a percent difference <30% thus demonstrating excellent reproducibility. These data are included in Attachment II.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

Orthohydroxy Atorvastatin

Runs 1 WAY through 4 WAY, 6 WAY, 13 WAY, and 31 WAY were qualification batches typically for analyst validation and did not contain subject samples. Of the remaining 58 runs, one run was rejected due to an extraction problem and two runs were rejected because the loading of the autosampler could not be verified. Two sample analysis runs failed due to QCs not meeting acceptance criteria and the remaining 52 sample analysis runs attempted for orthohydroxy atorvastatin met the acceptance criteria. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no peaks that interfered with orthohydroxy atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of orthohydroxy atorvastatin.

The only samples reassayed for orthohydroxy atorvastatin were due to extraction errors or quantitation above the highest calibration standard (6 samples). These samples were reassayed as dilutions and the repeat values agreed with the original extrapolated values within 12.5%. There was one run repeated for the parahydroxy metabolite only. The orthohydroxy atorvastatin data was not reported from this run; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 58 results compared, all agreed with a percent difference of <20% thus demonstrating excellent reproducibility. These data are included in Attachment III.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

Comments on Study AA05473/VZY

A review of 100% of the raw data associated with study AA05474/WAY was conducted. In addition, 100% of the chromatograms from this study were reviewed electronically. The 100% chromatograms were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no significant interfering peaks in the chromatograms from this study and integration was consistent and appropriate throughout the study.

Sample receipt and handling were reviewed and it was determined the sample chain of custody was intact. All samples were handled in accordance with method requirements. Also reviewed were the Certificates of Analysis for the reference standard and internal standard (if they were not USP standards), the stock weighings, solution preparation, blank plasma checks and batch extraction records.

This study was conducted between November 16, 2004 and January 31, 2005 under validation 90200/PWB and ZZ00410/WAU. A total of 68 sample analysis run were performed. The raw data (100%) was reviewed. The analyses for **atorvastatin**, **para-hydroxyatorvastatin** and **ortho-hydroxyatorvastatin** have been discussed below:

Atorvastatin

Run 1 VZY was a blank check that was not used. Runs 2 through 6 VZY, 13VZY, 14 VZY, 17 VZY and 58 VZY were qualification batches typically for analyst validation and did not contain subject samples. Runs 7 VZY, 12 VZY and 20 VZY were post-

preparative stability runs and did not contain subject samples. Of the remaining 55 sample analysis runs, one run was rejected due to an extraction problem and one run was rejected due to a technical error. One run was re-injected due to poor peak shape. Of the remaining 52 runs attempted for atorvastatin, only one run failed due to QCs not meeting acceptance criteria. The remaining 51 runs all met the acceptance criteria. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no interfering peaks with atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of atorvastatin.

Seventeen samples quantitated above the highest calibration standard and were re-assayed as dilutions. There was excellent agreement (16 samples agreed <12% difference, one sample agreed <25%) between the original extrapolated value and the reassay (diluted) value. On Run 15 VZY, it was noted Subject five Period three had anomalous levels for all three analytes. These samples were reassayed on run 55 VZY and the reassay did not confirm the original value. Run 15 VZY was rejected due to a processing error (the analyst most likely mixed these samples up) and all samples from this run were reassayed. The first repeat and second repeat values for atorvastatin were compared and the assays agreed within 20% for 16 samples and within 30% for the remaining two samples. There was one run repeated for metabolites only. The atorvastatin data was not reported from this run; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 54 results compared, 43 agreed with a percent difference of <20% and 8 samples agreed with a percent difference of <30%, and only three samples were greater than 30%, thus demonstrating excellent reproducibility. These data are included in Attachment IV.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

Para-hydroxyatorvastatin

Run 1 VZY was a blank check that was not used. Runs 2 through 6 VZY, 13VZY, 14VZY, 17VZY and58VZY were qualification batches typically for analyst validation and did not contain subject samples. Runs 7VZY, 12VZY and 20VZY were post-preparative stability runs and did not contain subject samples. Of the remaining 55 sample analysis runs, one run rejected due to an extraction problem and one run was rejected due to a technical error. Three runs were conducted for one of the other analytes and were not used for para-hydroxy torvastatin. Of the remaining 50 runs attempted for para-hydroxyatorvastatin, only one run failed due to QCs not meeting acceptance criteria.

The remaining 49 runs all met the acceptance criteria. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no peaks that interfered with parahydroxy atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of parahydroxy atorvastatin.

The only samples reassayed for parahydroxy atorvastatin were due to extraction errors. On Run 15 VZY, it was noted Subject five Period three had anomalous levels for all three analytes. These samples were reassayed on Run 55 VZY and the reassay did not confirm the original value. Run 15 VZY was rejected due to a processing error (the analyst most likely mixed these samples up) and all samples from this run were reassayed. There were two runs repeated for the other analytes. The parahydroxy atorvastatin data was not reported from these runs; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 94 results compared, 74 agreed with a percent difference of <20% and 16 samples agreed with a percent difference <30% and only 4 samples were greater than 30%, thus demonstrating excellent reproducibility. These data are included in Attachment V.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

Orthohydroxy Atorvastatin

Run 1 VZY was a blank check that was not used. Runs 2 through 6 VZY, 13VZY, 14 VZY, 17 VZY and 58 VZY were qualification batches typically for analyst validation and did not contain subject samples. Runs 7 VZY, 12 VZY and 20 VZY were post-preparative stability runs and did not contain subject samples. Of the remaining 55 sample analysis runs, one run was rejected due to an extraction problem and one run was rejected due to a technical error. One run was re-injected due to poor peak shape. Two runs were conducted for one of the other analytes and were not used for orthohydroxy atorvastatin. Of the remaining 50 runs attempted for orthohydroxy atorvastatin, only one run failed due to QCs not meeting acceptance criteria. The remaining 49 runs all met the acceptance criteria. The chromatograms (100%) were reviewed for the presence of interfering peaks, consistent and appropriate integration and any other anomaly that could impact the quality of the data. There were no peaks that interfered with orthohydroxy atorvastatin or its internal standard and the peaks were well resolved. There was no carryover noted in any of the runs and the blanks and pre-dose samples were clean at the retention time of orthohydroxy atorvastatin.

The only samples reassayed for orthohydroxy atorvastatin were due to extraction errors or quantitation above the highest calibration standard (15 samples). These samples were reassayed as dilutions and the repeat values agreed with the original extrapolated values within 22%. On Run 15 VZY, it was noted Subject five, Period three had anomalous levels for all three analytes. These samples were reassayed on Run 55 VZY and the reassay did not confirm the original value. Run 15 VZY was rejected due to a processing error (the analyst most likely mixed these samples up) and all samples from this run were reassayed. The first repeat and second repeat values for orthohydroxy atorvastatin were compared and the assays agreed within 20% for 20 samples and 41% for the remaining two samples. There was one run repeated for another analyte. The orthohydroxy atorvastatin data was not reported from this run; however, the repeat data was compared to the reported data for reproducibility purposes. Of the 60 results compared, 32 agreed with a percent difference of <20%, 10 agreed with a percent difference of <30% and 18 samples had a percent difference >30%. These data are included in Attachment VI.

There were no anomalous values detected during the review (quantifiable peaks in samples expected to be blank or samples expected to have levels and were blank).

3. ***Auditor's Conclusion:***

1. Based on the independent review of all data obtained for the validation of an LC/MS/MS assay for the determination of atorvastatin, para-hydroxy atorvastatin and ortho-hydroxyatorvastatin in human plasma, the method appears to be accurate, reproducible and suitable for its intended use. Adequate stability data has been generated under conditions of freeze thaw, room temperature, post-preparative storage, and long term frozen storage.

2. The sample analysis conducted in support of the two bioequivalence studies has also been independently reviewed and was found to meet current standards for acceptance. All reported data were from acceptable runs, interfering peaks were sufficiently low not to affect quantitation and the documentation supported the results. There were no significant issues identified in the validation or sample analyses that would affect the quality or integrity of the study conclusions.

Summary of the Conclusion from the Auditor: The auditors state that it is their opinion the validity of the data is sound and well-supported by the documentation that was reviewed.

Reviewer's Comments on the audit report:

The scope of the audit as stated is appropriate and adequate. The reported plasma concentration and pharmacokinetic parameters were confirmed by the auditors and deemed to be within SOPs. Therefore, the reviewer agrees with the auditor's conclusions that the assay method for atorvastatin, para-hydroxyatorvastatin and ortho-hydroxyatorvastatin and the study data as reported are sufficient and acceptable in demonstrating the bioequivalence of the test and reference products.

Overall Summary:

1. On Statistical Analysis - The firm's response on the statistical analysis is incomplete. The fasted study remains incomplete.

2. On para-hydroxyatorvastatin – The firm's response is satisfactory.

3. On Audit report – Based on the findings from the independent audit report by (b) (4) and (b) (4) of (b) (4) the analytical studies for both the fasted and fed bioequivalence studies on atorvastatin calcium tablets 80 mg are acceptable for review. However, the fasted BE study is still incomplete due to deficiencies in the statistical analysis of the study data.

The following deficiency comments should be forwarded to the firm:

Your study uses a two-treatment, three-period replicated crossover design. Your statistical analysis which did not include the subject-by-formulation interaction term is therefore not appropriate. In your analysis, the 90% confidence intervals were computed using the wrong error term. Our analysis, by modifying your proc mixed statements (to include the term subj*trt(seq)) and using the full dataset (i.e., all three periods), showed a statistically significant subject-by-formulation interaction ($p = 0.0161$ per REML fitting method) and 90% confidence intervals of 98.47% - 126.70% for Cmax. This result is similar to that obtained using the method described in the guidance (which also allows for the possibility of subject-by-formulation interaction).

Furthermore, your analysis, based on only the data from periods 1 and 2, 'Per(1,2)', is not acceptable. Using dataset 'Per(1,2)' is not an acceptable scenario due to artificially deleting the measures from the third period with no scientific reason. In addition, if using dataset 'Per(1,2)' is to be considered, then dataset 'Per (1,3)' should be checked too. The upper bound of the 90% confidence interval for dataset 'Per(1,3)' is 132.131% which is greater than the 125% bioequivalence limit.

Regarding your statement that " Therefore, the same approach with regards to the intra-variability estimation and SAS codes as for a 2-way crossover design had been identified a priori as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the protocol.", please note that the agency would not accept the results of an inappropriate analysis based on an unsuitable statistical analysis method mentioned in the protocol.

Therefore, your fasted study AA05474 remains incomplete since the 90% confidence intervals for atorvastatin Cmax are 98.5% - 126.7%, outside the acceptable limit of 80%-125%.

Recommendations:

The single-dose fasted BE study conducted by Lek Pharmaceuticals on its test product Atorvastatin Calcium Tablets, 80 mg (Lot # 3256108F) comparing it to the reference listed drug Lipitor® Tablets, 80 mg (Lot 06284V) remains unacceptable.

BIOEQUIVALENCE DEFICIENCIES

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. Your study uses a two-treatment, three-period replicated crossover design. Your statistical analysis which did not include the subject-by-formulation interaction term is therefore not appropriate. In your analysis, the 90% confidence intervals were computed using the wrong error term. Our analysis, by modifying your proc mixed statements (to include the term subj*trt(seq)) and using the full dataset (i.e., all three periods), showed a statistically significant subject-by-formulation interaction (p = 0.0161 per REML fitting method) and 90% confidence intervals of 98.47% - 126.70% for Cmax. This result is similar to that obtained using the method described in the guidance (which also allows for the possibility of subject-by-formulation interaction).

2. Furthermore, your analysis, based on only the data from periods 1 and 2, 'Per(1,2)', is not acceptable. Using dataset 'Per(1,2)' is not an acceptable scenario due to artificially deleting the measures from the third period with no scientific reason. In addition, if using dataset 'Per(1,2)' is to be considered, then dataset 'Per (1,3)' should be checked too. The upper bound of the 90% confidence interval for dataset 'Per(1,3)' is 132.131% which is greater than the 125% bioequivalence limit.

3. Regarding your statement that " Therefore, the same approach with regards to the intra-variability estimation and SAS codes as for a 2-way crossover design had been identified *a priori* as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the protocol.", please note that the agency would not accept the results of an inappropriate analysis based on an unsuitable statistical analysis method mentioned in the protocol.

Therefore, your fasted study AA05474 remains unacceptable since the 90% confidence intervals for atorvastatin Cmax are 98.5% - 126.7%, outside the acceptable limit of 80%-125%.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA# 77-575

Completed Assignment for 77575 ID: 4260

Back to Main Menu

Reviewer: Pradhan, Sikta **Date Completed:**
Verifier: , **Date Verified:**
Division: Division of Bioequivalence
Description:

Productivity:

ID	*Letter Date*	*Productivity Category*	*Sub Category*	*Productivity*	*Subtotal*		
4260	4/3/2007	Other	Study Amendment	1	1	Edit	Delete
4260	4/3/2007	Other	DSI Inspection Report	1	1	Edit	Delete
				Bean Total:	2		

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sikta Pradhan
12/20/2007 11:09:57 AM
BIOPHARMACEUTICS

Yih Chain Huang
12/20/2007 02:50:10 PM
BIOPHARMACEUTICS

Barbara Davit
12/20/2007 05:45:15 PM
BIOPHARMACEUTICS

DIVISION OF BIOEQUIVALENCE REVIEW

ANDA No. :	77-575
Drug Product Name:	Atorvastatin Calcium Tablets
Strength:	10 mg, 20 mg, 40 mg, and 80 mg
Applicant Name:	Lek Pharmaceuticals d.d.
Address:	Verovškova 57, SI-1526 Ljubljana, Slovenia
Submission Date(s):	3/6/2006 (response to deficiency comments)
Amendment Date(s):	
POC:	Barbara LoPiccolo (732-355-4053)
Fax:	609-395-2792
Reviewer:	Yih-Chain Huang, Ph.D.

I. Executive Summary

This submission contains the firm's response to DBE's deficiency comments of the original submission dated 02/11/2005 (v:/firmsam\Lek\ltrs&rev\77575N0205.doc). In the current amendment, the firm submitted the SAS codes used in its analysis of BE studies. Both fasted and fed studies were conducted using semi-replicate design (3-period, 2-sequence). However, the SAS Model used in the firm's data analysis is different from that recommended for the replicate design as described in the Statistical Guidance (Statistical Approaches to Establishing Bioequivalence) issued in January 2001. Therefore, the BE studies are still incomplete. There are other issues related to the studies: 1) The study samples for both fasted and fed studies were analyzed at (b) (4) (b) (4)) from (b) (4) for the fasted study and from (b) (4) for the fed study – within the time period of (b) (4) that the agency has concern about the validity of the assay, and 2) One of the active metabolites, para-hydroxyatorvastatin, failed on AUC and Cmax in the fasted study and Cmax in the fed study based on the firm's own analysis. Therefore, the application is still incomplete.

Deficiency Comments from the original review:

1. The atorvastatin Cmax in the fasting bioequivalence (BE) study AA05474 did not meet BE acceptance criteria of 80-125%. The 90% confidence intervals calculated by the Agency were 98.5-126.7%.

It is noted that you did not submit SAS Codes used in your analyses of the fasting study, despite our request. Thus, as we did not have this information, the Agency analysis was based on statistical procedures used for a fully replicated study.

2. Please submit the SAS codes for fasting BE study AA05474 as requested by the Agency. We previously requested this information; instead you resubmitted the SAS transport files.

Reviewer's comments:

1. The firm conducted its fasted and fed studies using a semi-replicate design (3-period, 2-sequence; ABB/BAA). From the SAS codes submitted, however, it appears that the firm has used a statistical model that is different from the model recommended in the agency's statistical guidance (Statistical Approaches to Establishing Bioequivalence, issued in January 2001) in its data analysis.

Model recommended in the guidance:

```
PROC MIXED;
CLASSES SEQ SUBJ PER TRT;
MODEL Y = SEQ PER TRT/ DDFM=SATTERTH;
RANDOM TRT/TYPE=FA0(2) SUB=SUBJ G;
REPEATED/GRP=TRT SUB=SUBJ;
ESTIMATE 'T vs. R' TRT 1 -1/CL ALPHA=0.1;
```

Model used by the firm:

(b) (4)



As noted in the original review, the 90% confidence interval (98.5-126.7%) on Cmax calculated by the DBE was outside the acceptance limits of 80-125%.

2. It should be noted that the study samples of both fasted and fed studies were analyzed at (b) (4) ((b) (4) from (b) (4) for the fasted study and from (b) (4) for the fed study. This is within the time period of (b) (4) (b) (4) that the agency has concern about the validity of the assay. The agency has notified the sponsor recently to confirm or repeat analytic studies used (see http://www.fda.gov/cder/news/pharmaco_studies/default.htm).

3. One of the active metabolites, para-hydroxyatorvastatin, failed AUC and Cmax in the fasted study and failed Cmax in the fed study (see detail in the attachment).

4. Therefore, the studies are incomplete.

Recommendations:

1. The fasted and fed studies conducted by LEK Pharmaceuticals on its test product Atorvastatin Calcium Tablets, 80 mg (Lot # 3256108F) comparing it to the reference product Lipitor® Tablets, 80 mg (Lot # 06284V) remain incomplete. The firm should be informed of comments #1 and #3.

.

Attachments:

1. Summary of statistical analysis (based on DBE's analysis as stated in the original review)

Table 1. Summary of Statistical Analysis for **Atorvastatin**								
Parameter	**Condition**							
	Fasted (N=50)				**Fed (N=48)**			
	PE		**90% CI**		**PE**		**90% CI**	
	Calculated by the firm	**Calculated by this reviewer**	**Calculated by the firm**	**Calculated by this reviewer**	**Calculated by the firm**	**Calculated by this reviewer**	**Calculated by the firm**	**Calculated by this reviewer**
AUC0-t	1.13	1.13	105.8-119.9	103.92-122.12	0.95	0.95	90.-100.3	90.33-100.49
AUC∞	1.12	1.12	105.1-119.0	103.34-121.25	0.95	0.95	90.4-100.1	90.29-100.33
Cmax	1.12	1.12	100.1-124.5	98.51-**126.72**	0.96	0.96	86.5-106.7	86.24-107.11

The fasted *in vivo* BE study does **NOT** meet the requirements for Cmax. The fed *in vivo* BE study meets the criteria for BE.

2. Additional information (including the analysis of metabolite data - obtained from the original review)

Single-dose Fasting Bioequivalence Study

Table E1. Study Summary, Fasting Bioequivalence Study	
Study No.	AA05474
Study Design	Open label, randomized, single dose, semi-replicate, 3-period, 2-sequence, 3-way crossover study
No. of subjects enrolled	50
No. of subjects completing	50
No. of subjects analyzed	50 (who completed at least two periods)
No. of subjects include in BE calculation	50 (who completed at least two periods)
Subjects (Healthy or Patients?)	Healthy
Sex(es) included (how many?)	Male: 27 Female: 23
Test product	Atorvastatin Calcium Tablets
Reference product	Lipitor® (Atorvastatin Calcium Tablets)
Strength tested	80 mg
Dose	1 X 80 mg tablet

Table E2. Summary of Statistical Analysis, Fasting BE Study[1]

Atorvastatin **Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals**				
Fasted Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	179.3	159.2	112.6	105.8-119.9
AUC∞	185.4	165.8	111.9	105.1-119.0
C_{max}	37.2	33.3	111.7	100.1-124.5
Ortho-Hydroxyatorvastatin **Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals**				
Fasted Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	238.02	228.5	104.2	97.2-111.6
AUC∞	243.9	236.5	103.1	96.6-110.1
C_{max}	30.02	30.7	97.9	87.0-110.2
Para-Hydroxyatorvastatin **Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals**				
Fasted Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	22.6	15.5	146.0	128.9-165.5
AUC∞	33.1	27.3	121.6	111.7-132.4
C_{max}	1.98	1.1	184.1	160.9-210.6

[1]Taken from firm's electronic tables with some modifications.

Reviewer's Comments: The 90% CI for Cmax calculated by this reviewer (98.5-126.7) for atorvastatin calcium was different than that reported by the firm (100.1-124.5). Therefore, Atorvastatin Calcium Tablets from Lek Pharmaceuticals failed the BE requirements under fasting conditions.

Table E6. Summary of Statistical Analysis, Fed BE Study[1]

Atorvastatin Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals				
Fed Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	179.9	188.9	95.2	90.4-100.3
AUC∞	185.9	195.4	95.2	90.4-100.1
C_{max}	42.9	44.7	96.0	86.5-106.7
Ortho-Hydroxyatorvastatin **Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals**				
Fed Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	216.9	219.2	99.0	95.1-103.0
AUC∞	223.09	225.99	98.7	95.0-102.6
C_{max}	30.7	29.3	104.6	95.9-114.2
Para-Hydroxyatorvastatin **Geometrics Means*, Ratio of Least-Squares Means, and 90% Confidence Intervals**				
Fed Bioequivalence Study				
Parameter	**Test**	**Reference**	**Ratio**	**90% C.I.**
AUC_{0-t}	21.8	18.7	116.1	109.0-123.7
AUC∞	30.4	27.1	112.1	105.9-118.8
C_{max}	2.9	1.6	139.4	126.7-153.3

[1]Taken from firm's electronic tables with some modifications.

BIOEQUIVALENCE DEFICIENCIES

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals, d.d.

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. We have reviewed the SAS codes used in your data analysis. Your statistical model is different from that recommended in the agency's statistical guidance "Statistical Approaches to Establishing Bioequivalence", issued in January 2001 for a replicated crossover study. Based on the agency's analysis, your atorvastatin Cmax in the fasting bioequivalence study AA05474 did not meet BE acceptance criterion of 80-125%. The 90% confidence interval calculated by the agency was 98.5-126.7%.

2. The results of one of the active metabolites, para-hydroxyatorvastatin, did not support that your test product is comparable with the reference product. Please explain why DBE should consider your test product is bioequivalent to the reference product based on these data.

Sincerely yours,

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

BIOEQUIVALENCE - INCOMPLETE Submission date: 3/6/2006

Study Amendment (STA) Strengths: ALL
Outcome: IC

Outcome Decisions:
IC - Incomplete

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Yih Chain Huang
3/5/2007 04:21:30 PM
BIOPHARMACEUTICS

Barbara Davit
3/5/2007 04:43:02 PM
BIOPHARMACEUTICS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 077575

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ROUTING SHEET

☒ APPROVAL ☐ TENTATIVE APPROVAL ☐ SUPPLEMENTAL APPROVAL (NEW STRENGTH) ☐ CGMP

Division: III	Team: 34	PM: Bob Gaines

Electronic ANDA: Yes ☒ No ☒

ANDA #:077575
Firm Name:Sandoz Inc.
ANDA Name:Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg
RLD Name:Lipitor Tablets (20702 by Pfizer)

Electronic AP Routing Summary Located:
V:\Chemistry Division III\Team 34\Electronic AP Summary\77575.ap.doc

AP/TA Letter Located:
V:\Chemistry Division III\Team 34\Final Version For DARRTS Folder\APPROVAL LETTERS\77575.apltr.DOC

Project Manager Evaluation: **Date: 5/16/12 Initials:** RG

☐ Previously reviewed and tentatively approved --- Date n/a
☐ Previously reviewed and CGMP Complete Response issued -- Date n/a

Original Rec'd date 2/18/2005	Date of Application 2/11/2005	Date Acceptable for Filing 2/18/2011
Patent Certification (type) PIV	Date Patent/Excl. expires 2015,2017,2013	Citizens' Petition/Legal Case? Yes☐ No ☐ (If YES, attach email from PM to CP coord)
First Generic Yes ☐ No ☒ **DMF#:** 18082 (provide MF Jackets)	Priority Approval (Top 100, PEPFAR, etc.)? Yes ☒ No ☐ Comment: Press release to be created by OCC. Prepared Draft Press Release sent to Cecelia Parise Yes ☐ No ☐ Date:	
☐ Suitability Petition/Pediatric Waiver	Pediatric Waiver Request: Accepted ☐ Rejected ☐ Pending ☐	

EER Status: ☒ Pending ☐ Acceptable ☐ OAI *EES Date Acceptable:*_____ ☐ Warning Letter Issued; Date:
Has there been an amendment providing for a Major change in formulation since filling? Yes ☐ No ☒ Comment:
Date of Acceptable Quality (Chemistry) 9/22/2011; 11/23/11 Addendum Needed: Yes ☐ No ☐ Comment:
Date of Acceptable Bio 5/7/2010 Bio reviews in DARRTS: Yes ☐ No ☐ (Volume location:)
Date of Acceptable Labeling 4/20/12 Attached labeling to Letter: Yes ☐ No ☐ Comment:
Date of Acceptable Sterility Assurance (Micro) n/a

Methods Val. Samples Pending: Yes ☐ No ☒; Commitment Rcvd. from Firm: Yes ☐ No ☐

Post Marketing Agreement (PMA): Yes ☐ No ☒ (If yes, email PM Coordinator) Comment:

Modified-release dosage form: Yes ☐ No ☒ (If yes, enter dissolution information in Letter)

Routing:

☒ Labeling Endorsement, Date emailed: 5/16/12 REMS Required: Yes ☐ No ☒ REMS Acceptable: Yes ☐ No ☐

☒ Regulatory Support

☒ Paragraph 4 Review (Dave Read, Susan Levine), Date emailed: 5/21/12

☒ Division

☐ 1st Generic Review

☒ Bob West / Peter Rickman
☐ Keith Webber

☒Filed AP Routing Summary in DARRTs	☒Notified Firm and Faxed Copy of Approval Letter	☒ Sent Email to "CDER-OGDAPPROVALS" distribution list

OGD APPROVAL ROUTING SUMMARY

1. ***Regulatory Support Branch Evaluation***

Martin Shimer **Date: 9/26/2011,**

Chief, Reg. Support Branch **Initials:** MHS

Contains GDEA certification: Yes ☒ No ☐	Determ. of Involvement? Yes ☐ No ☒
(required if sub after 6/1/92)	Pediatric Exclusivity System
	RLD = Lipitor NDA# 20-702 Date Checked Granted Nothing Submitted ☐ Written request issued ☐ Study Submitted ☐
Patent/Exclusivity Certification: Yes ☒ No ☐ If Para. IV Certification- did applicant: Notify patent holder/NDA holder Yes ☒ No ☐ Was applicant sued w/in 45 days:Yes ☐ No ☒ Has case been settled: Yes ☐ No ☐ Date settled: Is applicant eligible for 180 day	
Generic Drugs Exclusivity for each strength: Yes ☐ No ☒	
Date of latest Labeling Review/Approval Summary _____	
Any filing status changes requiring addition Labeling Review Yes ☐ No ☒	

Type of Letter:
☒ APPROVAL ☐ TENTATIVE APPROVAL ☐ SUPPLEMENTAL APPROVAL (NEW STRENGTH) ☐ CGMP
☐ OTHER:

Comments:ANDA submitted on 2/18/2005, BOS=Lipitor NDA 20702, PIII to '893 exp. 3/24/2010 and '995 exp. 6/28/2011, PIV to '104, '156 and '971. ANDA ack for filing with a PIV for the 10 mg, 20 mg, 40 mg and 80 mg strengths on 2/18/2005 (LO dated 4/15/2005). Patent Amendment rec'd on 8/29/2005-firm states that they were not sued within 45 days on any of the PIV certs (no RR's provided). Patent Amendment rec'd on 7/15/2005-RR from Pfizer in NY, NY signed and dated 5/9/2005(notice sent on 5/3/2005), RR from Warner-Lambert in Ann Arbor MI signed and dated 6/14/2005(notice sent 6/9/2005), notice sent to Warner Lambert in Morris Plains NJ (notice sent on 6/2/2005). Patent Amendment rec'd on 6/16/2010-PIII to '893, '995, and RE667, PIV to '104, '156 and '971-these patent certs represent a change only in that the sponsor submitted a PIII cert to the RE667 patent, all other certifications remained the same. It is noted that the RE667 patent expired on 6/28/2011. Patent Amendment rec'd on 6/15/2011-cover letter expresses the sponsor's position that they are eligible for Full Approval upon the expiration of the RE667 patent on 6/28/2011.

Application is eligible for TA only as they are blocked by Ranbaxy's eligibility for 180 day exclusivity.

Update 5/18/2012-At this time the only three unexpired patents are the '104, '156 and '971 patents. Sandoz challenged each of these patents and was not sued by the innovator within 45 days. Therefore none of these patents is a barrier to the approval of this ANDA. The last remaining barrier is Ranbaxy's eligibility for 180 day exclusivity. Ranbaxy triggered their exclusivity period with the commercial marketing of ANDA 76-477, with their exclusivity period expiring on 5/28/2012. This date is a Monday and a Federal Holiday. Therefore, this ANDA will be eligible for Full Approval on or

after Tuesday the 29th of May 2012.

2. ***Labeling Endorsement***

Reviewer, BT:
Date5/17/12
InitialsBT/RG for

Labeling Team Leader, RW:
Date5/17/12
InitialsRW/RG for

REMS required?
☐Yes ☒No

REMS acceptable?
☐Yes ☐No ☒n/a

Comments:

From: Wu, Ruby (Chi-Ann)
Sent: Thursday, May 17, 2012 8:31 AM
To: Turner, Betty; Gaines, Robert
Subject: RE: ANDA 77575

I concur.

Hi Bob,

Do you want to add "(base)" after the strength?

Ruby

From: Turner, Betty
Sent: Wednesday, May 16, 2012 3:31 PM
To: Gaines, Robert; Wu, Ruby (Chi-Ann)
Subject: RE: ANDA 77575

Hi Bob,

In the AP letter, first paragraph, can you include "80 mg" on the third line.

I have checked the OB, Drugs@fda website, USP, DARRTS, REMS and Medwatch for updates. There are no new changes for the labeling since last review was completed.

Thanks,

Betty

From: Gaines, Robert
Sent: Wednesday, May 16, 2012 2:50 PM
To: Turner, Betty; Wu, Ruby (Chi-Ann)
Subject: ANDA 77575

Hi Betty and Ruby.

The subject Atorvastatin application by Sandoz is ready for full approval. Please provide labeling endorsement.

Thanks

Bob

<< File: 77575 label rev.pdf >> << File: 77575.apltr.DOC >>

3. ***Paragraph IV Evaluation*** **PIV's Only**

David Read — **Date 21May2012**
OGD Regulatory Counsel — **InitialsDTR**

Pre-MMA Language included ☐
Post-MMA Language Included ☐
Comments:Changes to AP letter saved to V drive.

4. ***Quality Division Director /Deputy Director Evaluation*** — **Date 5/22/12**

Chemistry Div. **III (Sayeed)** — **InitialsVAS**

Comments:cmc satisfactory.

5. ***First Generic Evaluation*** **First Generics Only**

Frank Holcombe — **Date 5/25/12**
Assoc. Dir. For Chemistry — **Initials rlw/for**

Comments: (First generic drug review)
N/A. Ranbaxy's ANDA 76-477 for this drug product was approved on 11/30/11.

OGD Office Management Evaluation

6. Peter Rickman **Date 5/25/12**
Director, DLPS **Initials rlw/for**

Para.IV Patent Cert: Yes☐ No☐
Pending Legal Action: Yes ☐ No ☐
Petition: Yes☐ No☐
Comments: Bioequivalence studies (fasting and non-fasting) on the 80 mg strength found acceptable. In-vitro dissolution testing for all 4 strengths found acceptable. Waivers granted under 21 CFR 320.22(d)(2) for the 10 mg, 20 mg and 40 mg tablet strengths. Bio study sites have acceptable OSI inspection histories. Office-level bio endorsed 5/7/10.

Final-printed labeling (FPL) found acceptable for approval 4/20/12 (Approval Summary #2) , as endorsed 5/17/12. No REMS is required.

CMC found acceptable for approval (Chemistry Review #6 - Addendum #2) 5/18/12.

AND/OR

7. Robert L. West **Date 5/25/12**
Deputy Director, OGD **Initials RLWest**

Para.IV Patent Cert: Yes☒ No☐
Pending Legal Action: Yes☐ No☒
Petition: Yes☐ No☒
Press Release Acceptable ☐
Date PETS checked for first generic drug _____

Comments: Acceptable EES dated 5/25/12 (Verified 5/25/12). No "OAI" Alerts noted.

Sandoz provided paragraph IV certifications to the '104, '156 and '971 patents, but was not sued on any patent within the 45-day period. There are no additional unexpired patents or exclusivity currently listed in the "Orange Book" for this drug product.

Ranbaxy's 180-day generic drug exclusivity for Atorvastatin Calcium Tablets will expire on May 28, 2012.

This ANDA is eligible for final approval upon expiration of Ranbaxy's 180-day exlcusivity. As the exclusivity will expire on a non-work day, final approval will be granted on May 29, 2012.

8. ***OGD Director Evaluation***
   Keith Webber
   Deputy Director, OPS
   Comments: RLWest for Keith Webber, Ph.D. 5/25/12.
   First Generic Approval ☐
   PD or Clinical for BE ☐
   Special Scientific or Reg.Issue ☐
   Press Release Acceptable ☐

   Comments:

9. Project Manager
   Date 5/29/12
   Initials RG

   Check Communication and Routing Summary into DARRTS

Orange Book Report:

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

- 
-  [1]
-  [2]

- FDA Home[3]
- Drug Databases[4]
- Orange Book[5]

-

Patent and Exclusivity Search Results from query on Appl No 020702 Product 004 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N020702	004	5686104	Nov 11, 2014		Y	U - 213	
N020702	004	5686104*PED	May 11, 2015			U - 213	
N020702	004	5969156	Jul 8, 2016	Y			
N020702	004	5969156*PED	Jan 8, 2017				
N020702	004	6126971	Jan 19, 2013		Y		
N020702	004	6126971*PED	Jul 19, 2013				

Exclusivity Data

There is no unexpired exclusivity for this product.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT T GAINES
05/29/2012

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 25, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-25-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 24, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-24-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-23-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 22, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-22-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 21, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-21-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 18, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-18-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 17, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-17-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 16, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-16-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 15, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

05-15-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 14, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-14-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 11, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-11-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 10, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-10-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 9, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

05-09-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 8, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-08-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 7, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-07-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 4, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-04-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 3, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-03-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 2, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-02-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 1, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

05-01-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 30, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-30-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 27, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-27-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 27, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– MINOR AMENDMENT –

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
MINOR AMENDMENT – RESPONSE TO FDA REQUEST DATED APRIL 24, 2012

Dear Sir/Madam:

Sandoz Inc. hereby submits a "Minor Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the April 24, 2012 telephone conversation between Mr. Bob West, FDA, and Ms. Bernadette Attinger of Sandoz. During this conversation, Mr. West stated that since Final Approval is expected by the end of May, a Tentative Approval will not be issued at this time due to the short time frame. Mr. West further requested that Sandoz Inc. submit a Minor Amendment referencing the April 24, 2012 telephone correspondence along with confirmation that no CMC changes have been made since the last amendment.

As per the Agency's request, Sandoz Inc. hereby confirms that no changes have been made to the Chemistry, Manufacturing, and Controls (CMC) section since the last CMC telephone amendment submitted on October 26, 2011. Therefore Sandoz Inc. looks forward to the approval of ANDA 077575 for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg on May 28, 2012.

This amendment is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 26, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	**Dec 28,2010**	**Warner-Lambert**	**Jun 28, 2011**
5686104	**Nov 11, 2014**	**Warner-Lambert**	**May 11, 2015**
5969156	**Jul 8, 2016**	**Warner-Lambert**	**Jan 8, 2017**
6126971	**Jan 19, 2013**	**Warner-Lambert**	**Jul 19, 2013**
RE40667	**Dec 28, 2010**	**Warner-Lambert**	**Jun 28, 2011**
8,026,376	**May 13, 2027**	**Pfizer Inc.**	**Nov 23, 2027**

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-26-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 25, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-25-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 24, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-24-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-23-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 17, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-17-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 20, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

04-20-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 19, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-19-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 18, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-18-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 16, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-16-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 13, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-13-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 12, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-12-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 11, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-11-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 10, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Christopher Allen for

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

04-10-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 9, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-09-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 6, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

04-06-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 5, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-05-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 4, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-04-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 3, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-03-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

April 2, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

04-02-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 30, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-30-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 29, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-29-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 28, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-28-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 27, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-27-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-26-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 26, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-23-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– LABELING AMENDMENT–

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg

LABELING AMENDMENT – Revised labeling subsequent to RLD changes approved on February 28, 2012

Dear Sir/Madam:

Sandoz Inc. hereby submits, a "Labeling Amendment" to the pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

This amendment is being submitted to provide the revised labeling as per the Reference Listed Drug (LIPITOR®) labeling changes approved on February 28, 2012. The revised package insert and patient information leaflet in final printed format are provided.

To facilitate review, a side-by-side comparison of proposed labeling with the previously submitted labeling with all differences annotated and explained is also provided in this submission.

The following documents are included in this submission:

- 356h
- cover-letter
- package insert and patient package insert (word & pdf)
- side-by-side comparison

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This amendment is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 22, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-22-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 21, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-21-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 20, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-20-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 19, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-19-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 16, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-16-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 15, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-15-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 14, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-14-2012

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 13, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-13-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 12, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-12-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 9, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-09-2012

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 8, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-08-2012

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 7, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-07-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 6, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-06-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 5, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

03-05-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 2, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

03-02-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 1, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609 627 8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

03-01-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 29, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-29-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 28, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

02-28-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 27, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

02-27-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 24, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-24-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-23-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 22, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-22-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 21, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-21-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 17, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-17-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 16, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-16-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 15, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-15-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 14, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-14-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 13, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-13-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 10, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

02-10-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 09, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-09-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 08, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-08-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 07, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-07-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 06, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

02-06-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 03, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-03-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 02, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-02-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

February 01, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

02-01-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 31, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-31-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 30, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-30-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 27, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-27-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 26, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-26-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 25, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-25-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 24, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

01-24-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 23, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-23-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 20, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-20-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 19, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-19-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 18, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-18-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 17, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-17-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 16, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-16-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 13, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-13-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 12, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-12-2012

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 11, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-11-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 10, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

01-10-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 09, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-09-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 06, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

01-06-2012
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 05, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

01-05-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 04, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

01-04-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

January 03, 2012

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

01-03-2012
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 30, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

12/30/2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 29, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12/29/2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 28, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12/28/2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 27, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

12/27/2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 23, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12/23/2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 22, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

12/22/2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 21, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

12/21/2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 20, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA**)** for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12/20/2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 19, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via on October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

12-19-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 16, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-16-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 15, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-15-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 14, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-14-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 13, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-13-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 12, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-12-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 09, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-09-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 08, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-08-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 07, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-07-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 06, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-06-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 05, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-05-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 02, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-02-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

December 01, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

12-01-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 30, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-30-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: November 30, 2011

FROM: Robert L. West, Deputy Director, Office of Generic Drugs, CDER

TO: ANDA 078773 (Teva)
ANDA 077575 (Sandoz)
ANDA 090548 (Apotex)
ANDA 091226 (Mylan/Matrix)

SUBJECT: Pre-Launch Activities Importation Requests (PLAIRs); Atorvastatin ANDAs

The Agency is in the process of developing a Guidance regarding pre-launch activities importation requests (PLAIRs). In the past, requests to permit importation of such unapproved finished dosage form drug products have been reviewed and informally granted or denied.[1] Recently the Agency has sought to standardize the process regarding how a PLAIR should be submitted and the circumstances under which the Agency may grant a PLAIR. This memorandum, the purpose of which is to explain the background under which the PLAIRs for ANDA 078773 (Teva), ANDA 077575 (Sandoz), ANDA 090548 (Apotex) were granted, reflects much of the work that has been done in developing the Guidance.

BACKGROUND

To allow domestic drug manufacturers to prepare and position products for market launch in anticipation of NDA/ANDA approval, for many years FDA has used its enforcement discretion and permitted certain interstate shipments of unapproved products in finished dosage form. (Such shipments have been allowed under certain controls and restrictions; for example, products may only be shipped to facilities identified in a pending NDA or ANDA or to facilities owned and controlled by the applicant.) Because foreign firms must bring their products through Customs, such an informal scheme has certain drawbacks. FDA's PLAIR program allows, on a case-by-case basis, the importation and warehousing of finished drugs when an NDA or ANDA is pending. The PLAIR program was developed to formalize the Agency's historical use of enforcement discretion and to allow foreign and domestic manufacturers to operate on a more or less equal footing in their ability to prepare and position products for rapid market launch upon approval.

[1] Section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) prohibits the introduction or delivery for introduction into interstate commerce of a new drug "unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." Section 801(a)(3) of the Act states that a drug may be refused admission into the United States if, among other things, it appears that it violates section 505 of the Act.

It is the choice of an applicant who has a pending NDA or ANDA whether or not to submit a PLAIR. The unapproved finished dosage form drug products should either be in final packaged form or require minimal further processing, such as final packaging and/or labeling. A PLAIR includes information such as the drug product name and how supplied, the NDA or ANDA number, the name and address of the foreign manufacturer of the finished drug product, the name and address of the U.S. consignee, the name and address of the warehouse or distribution facility controlled by or under contract with the applicant where the finished dosage form product in final packaged form will be stored pending approval. A PLAIR also should include a signed statement that neither the applicant nor its consignees or distributors will sell, offer for sale, or distribute the drug product in U.S. commerce until FDA has approved the NDA or ANDA. When finished dosage form drug product in bulk is imported for further processing, a PLAIR includes information regarding the facility where further processing activities will occur, including the name and address of the facility, a description of the further processing activities, and information about where the finished dosage form product in final packaged form will be stored pending approval.

An ANDA applicant should not submit a PLAIR until after FDA has determined that the chemistry, manufacturing, and control (CMC) portion is acceptable. For an ANDA that is tentatively approved, a PLAIR should be submitted no more than 60 days prior to the anticipated full approval. Applicants submit a PLAIR by e-mail and one PLAIR should be submitted for each NDA or ANDA. After review of the PLAIR, the CDER Office of Drug Security, Integrity and Recalls (ODSIR), Division of Import Operations and Recalls notifies the applicant whether the PLAIR has been granted. The notification is sent by e-mail to the applicant, the appropriate CDER review division, and the Office of Regulatory Affairs/Division of Import Operations.[2]

Drug products offered for importation under a granted PLAIR are detained by FDA as unapproved drugs. However, rather than issuing a refusal of admission, the Agency exercises enforcement discretion and keeps the detention in place until the Agency either approves the NDA/ANDA or for 6 months, whichever occurs first. The drug product will be subject to refusal and either destruction or exportation if the Agency does not approve the sponsor's NDA/ANDA or if 6 months have passed since the entry date of the initial shipment under a PLAIR.

FDA's determination to grant a PLAIR is subject to the applicant's meeting the following conditions:

1. The PLAIR submission contains a written certification that neither the applicant nor the applicant's consignee will sell, offer for sale, or further distribute in domestic commerce the drug product without an approved application for the drug product.

2. The responsible foreign facility has a satisfactory inspectional history and is either the subject of an ongoing FDA GMP inspection or is in substantial conformity with applicable good manufacturing practices (21 CFR parts 210 and 211).

[2] If there are any changes made after the original PLAIR submission, an amended PLAIR should be submitted. If it is acceptable, CDER ODSIR will notify ORA of the amendment.

3. Bulk unapproved finished dosage form drug products are to be delivered to a facility identified in the pending NDA or ANDA to permit further processing, after which the products should remain at the facility where the processing occurred or be transferred to a single site controlled by or under contract with the applicant. For unapproved finished dosage form drug products in final packaged form that do not require further processing, the applicant should state that the drug products will be delivered to a single site controlled by or under contract with the applicant. In both cases, the products should remain under quarantine pending final approval of the application, and remain subject to the terms and conditions of the U.S. Customs and Border Protection entry bond that covers the importation of the specific shipment. Warehouse/distribution facilities controlled by or under contract with the applicant must comply with applicable cGMPs, including proper storage conditions and appropriate temperature and humidity controls. See 21 CFR 211.42 and 211.46; see also 21 CFR 205.50(c)

Upon receiving notice from FDA that the NDA/ANDA is approved, the applicant should send a copy of the approval letter by e-mail to the district office. FDA will determine whether the product that was imported under a PLAIR meets all the requirements of the approved application. FDA's decision to grant a PLAIR is not binding on the Agency. The granting of a PLAIR is not a promise to approve the full application at any future time period and companies who import in reliance on a PLAIR do so at their own risk. FDA may elect to refuse admission of a drug if, for example, the applicant distributes the unapproved drug product in a manner not specified under the granted PLAIR, or 6 months have passed since the entry date of the initial shipment under a PLAIR and approval of the NDA or ANDA has not been granted. Within 90 days of an Agency decision to refuse admission into the United States, articles must be exported or destroyed, as required by section 801(a) of the Act. The Agency has encountered instances in which drug products that had been warehoused subject to a pending NDA/ANDA approval did not conform with late changes made to the approved drug product labeling, or instances in which the NDA/ANDA did not receive FDA approval.

ATORVASTATIN

The applicants of the four atorvastatin ANDAs to which this memorandum is addressed have each submitted a PLAIR. The PLAIRs of Teva, Sandoz, and Apotex were approved on November 21, 2011. As of the date of this memo, no decision has been made on the PLAIR of Mylan/Matrix.

All four of these ANDAs were submitted after ANDA 076477 was submitted by Ranbaxy. Ranbaxy's ANDA 076477 was the first substantially complete ANDA submitted with paragraph IV certifications to the patents listed in the Orange Book for Pfizer's Lipitor. Because of this, Ranbaxy is eligible for 180-day generic drug exclusivity.

The very complicated situation with atorvastatin is explained in detail elsewhere in the administrative records of the atorvastatin ANDAs (largely in Ranbaxy's ANDA 076477), and will not be repeated here. However, in summary, the status of Ranbaxy's ANDA has been the subject of widespread speculation, and the possibility of certain subsequent applicants being eligible for immediate full approval under various scenarios has also been widely speculated

upon. FDA, moreover, does not have full knowledge of all aspects of the situation. In particular, there may (or may not) be contractual arrangements between the various parties, including Ranbaxy, the details of which may (or may not) affect the ability of one or more subsequent applicants to be fully approved before the expiration of Ranbaxy's 180-day exclusivity period.

The ANDAs of the four PLAIR applicants are all at an advanced stage of review.[3] In fact, during the month of November, OGD was anticipating that most, and perhaps all four, might be tentatively approved. To the best of our knowledge on November 21, when three of the PLAIRs were granted, Ranbaxy was eligible for 180-day exclusivity, and Ranbaxy's earliest launch date would be November 30, 2011 (as widely reported for more than three years, based on their 2008 settlement agreement with Pfizer). This would mean that no subsequent applicant could be approved until May 28, 2012, at the earliest, which being more than 6 months from November 21, 2011, is hardly "imminent" (at least one applicant claimed in its PLAIR that approval of its ANDA was imminent.) This, however, is not grounds for denying the PLAIR particularly in circumstances like those present here where applicants are aware of the exclusivity and considering whether to challenge it and/or to strike a deal that permits marketing before the exclusivity runs.

The PLAIRs were voluntarily submitted by the four applicants, and it is fair to assume that these applicants were fully aware of Ranbaxy's status as a first applicant and the significance of November 30. It is also fair to assume that these applicants are aware that the granting of a PLAIR is no guarantee of ANDA approval, imminent or otherwise, and that drug product will be subject to refusal and either destruction or exportation if 6 months have passed since the entry date of the initial shipment under a PLAIR. These are known risks. As noted above, the Agency does not necessarily know what has happened (or perhaps will happen) with respect to Ranbaxy's exclusivity. The possibility exists that Ranbaxy could, perhaps even in the very near future, relinquish or selectively waive its exclusivity, thereby permitting the approval of one or more of the PLAIRs ANDAs, assuming of course the ANDA is otherwise eligible for approval.

[3] According to our records, the CMC portions of ANDA 078773 (Teva), ANDA 077575 (Sandoz), ANDA 090548 (Apotex) all were considered "acceptable" when the PLAIRs were granted on Nov. 21. The record shows that, at that time, FDA was still in the process of finalizing its resolution of certain issues pertaining to these ANDAs and the current USP monograph for atorvastatin calcium. As of Nov 21, however, it appeared that the three ANDAs in question would meet the standards of identity in the current USP monograph. With regard to ANDA 091226 (Mylan/Matrix), there were impurity issues that, as of the date of this memorandum, were not yet fully resolved and therefore have precluded an "acceptable" finding.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LEIGH A SEARS
11/30/2011

ROBERT L WEST
11/30/2011
Deputy Director, Office of Generic Drugs

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: November 17, 2011

FROM: Paul Schwartz, Ph.D.
Associate Director for Product Quality Coordination
Office of Generic Drugs

THROUGH: Lawrence X. Yu, Ph.D.
Deputy Director for Science and Chemistry
Office of Generic Drugs

SUBJECT: API Sameness

TO: ANDA 077575 - Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, 80 mg
Sandoz Inc.

The Reference Listed Drug for generic atorvastatin calcium tablet applications is Pfizer's Lipitor, NDA 020702. The drug substance (or active ingredient) used by Pfizer to manufacture Lipitor is atorvastatin calcium. The atorvastatin calcium is the calcium salt (2:1) trihydrate of atorvastatin, a crystalline form of the molecule. The drug substance used by Sandoz in ANDA 077575 is atorvastatin calcium; it is (b) (4) and in (b) (4) form.

There is a USP monograph for the atorvastatin calcium drug substance. Upon consideration of the USP monograph, FDA has determined that an ANDA applicant for generic atorvastatin calcium tablets can demonstrate active ingredient "sameness" for the purposes of section 505(j) by demonstrating that the active ingredient meets the standards for identity in the atorvastatin calcium drug substance monograph. The question considered in this memorandum is whether the active ingredient in Sandoz's ANDA meets the standards for identity in the monograph notwithstanding differences in polymorphic form.

Both the trihydrate and the (b) (4) forms are listed in the USP monograph. The USP is silent, however, on the polymorphic form of the drug substance. The USP Atorvastatin Calcium Reference Standard is the trihydrate crystalline form as in the Pfizer product. The USP Identification test indicated for use in the atorvastatin calcium drug substance monograph includes infrared absorption as described in USP chapter <197>. To pass the infrared absorption identification test, the test sample must exhibit peaks (maxima) only at the same wavelengths as the USP Reference Standard (USPRS). Since the drug substance used by Sandoz is in a different polymorphic form from that of the USPRS for atorvastatin calcium, the infrared spectra by the IR method do not match peak to peak.

The USP, noting that "[d]ifferences that may be observed in the spectra so obtained sometimes are attributed to the presence of polymorphs," provides that [u]nless otherwise directed in the individual monograph, therefore continue as follows. …dissolve equal portions of the test specimen and the Reference Standard in equal volumes of a suitable solvent, evaporate the solutions to dryness in similar containers under identical conditions and repeat the test on the residues." USP General Chapter <197>. This method is termed "the modified IR method."

Since the USP drug substance monograph for atorvastatin calcium does not direct otherwise, it is permissible for Sandoz to use the modified IR method. When Sandoz used this USP modified IR method, the spectra matched those from the RLD. These results were confirmed by the FDA's Division of Pharmaceutical Analysis in St. Louis. The FDA laboratory concluded that the IR peaks matched and therefore the Sandoz drug substance passed the USP Identification test.

USP's recognition that differences may be observed due to the presence of polymorphs, and its provision of the modified IR method, are consistent with the agency's position on polymorphs in demonstrating active ingredient "sameness" for the purposes of ANDAs that is set forth in the agency's guidance for industry entitled *ANDAs: Pharmaceutical Solid Polymorphism* (July 2007). This guidance states that "differences in drug substance polymorphic forms do not render drug substances different active ingredients for the purposes of ANDA approvals within the meaning of the [Federal Food, Drug and Cosmetic Act] and FDA regulations." Id. at 5.

Accordingly, it is concluded that while the drug substance used in Sandoz's atorvastatin calcium tablets is in a different polymorphic form from that in the Pfizer Lipitor product, it is considered to be the same active ingredient because the Sandoz drug substance meets the standards of identity as prescribed in the current USP monograph for atorvastatin calcium.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LEIGH A SEARS
11/30/2011

ROBERT L WEST
11/30/2011
Deputy Director, Office of Generic Drugs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 29, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-29-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 28, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-28-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

From: CDER-OC-PLAIR
Sent: Monday, November 21, 2011 1:42 PM
To: 'giovanna.trower@sandoz.com'
Cc: Notzon, Stella; CDER-OC-PLAIR
Subject: FW: PLAIR REQUEST FOR ANDA 77-575, ATORVASTATIN CALCIUM TABLETS - Granted

Importance: High

Attachments: PLAIR REQ ATORVASTATIN 77575 11-01-2011.pdf.zip; PLAIR-Atorvastatin.PDF

Dear Giovanna,

At this time, FDA, Center for Drug Evaluation and Research (CDER) will exercise enforcement discretion to allow the importation of ANDA 77575 ATORVASTATIN Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg under the Pre-Launch Activities Importation Request (PLAIR).

Please make sure that your firm is registered and once the application has been approved you must list your drug product.

Stella Notzon (ORA contact above) must be notified, in advance, of the entry number involved that your company is importing under this PLAIR enforcement discretion. Please keep in mind that the amount of product imported into the US must match with what you stated in the PLAIR request. Otherwise, an amended PLAIR must be submitted to CDER-OC-PLAIR@fda.hhs.gov for an "enforcement discretion" which supersedes all enforcement discretion provided. You may make the changes on the initial PLAIR request, however please identify the document as an "amendment" to differentiate it from the initial PLAIR request which ensures expeditious review and response. Once your application has been approved, please provide us (CDER-OC-PLAIR and ORA/DIOP) with a copy of the approval letter.

Note: only one shipment ready for launching referring to one import entry regardless of the quantity, batches or lot numbers offered for imports will be acceptable.

Thanks,

ORA/DIOP Contact:

Stella Notzon

Import Operations and Policy Branch

Main no.: 301-796-6678

Fax: 301-827-4086

CDER contacts:

Marybet Lopez, CSO/CO

CDER/Import & Export Team

(301) 796-3213

CDER-OC-PLAIR@fda.hhs.gov

Michelle Dillahunt, CSO/CO

CDER/Import & Export Team

From: giovanna.trower@sandoz.com [mailto:giovanna.trower@sandoz.com]
Sent: Tuesday, November 01, 2011 11:52 AM
To: CDER-OC-PLAIR
Subject: PLAIR REQUEST FOR ANDA 77-575, ATORVASTATIN CALCIUM TABLETS
Importance: High

Dear Import and Export Team,

Please find attached the Sandoz PLAIR request for Atorvastatin Calcium Tablets, ANDA 77575.

Please let me know if you need additional information for evaluating the PLAIR.

Best regards,

Giovanna Peterkin Trower
Sandoz Inc.
GX, Ra Regulatory & Audit-Dev
USPR, CSB - 103L
Sandoz Inc. - a Novartis Company
506 Carnegie Center, Suite 400
Princeton, NJ 08540
USA
Phone: +1 609 627-5211
Fax: +1 609 395-2792
Email : giovanna.trower@sandoz.com



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LEIGH A SEARS
11/28/2011

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 25, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-25-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 23, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-23-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Memo to File for ANDA 77575 (Atorvastatin Calcium Tablets)

Review cycle # 5 dated Oct 6, 2011 (in darrts) is incomplete as additional information was requested from the firm for the confirmation of IR identification test for the API to meet the current USP monograph.

Gil J Kang
11/23/2011

V:\Chemistry Division III\Team 31\ANDA REVIEWS\Gil\77575memo_23NOV2011.doc

---

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
11/23/2011

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 22, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-22-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 21, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

11-21-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 18, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-18-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 17, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-17-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 16, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-16-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 15, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-15-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 14, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-14-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 11, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-11-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 10, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-10-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 09, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-09-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 08, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-08-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 07, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-07-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 04, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-04-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 03, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-03-2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 02, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

11-02-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 01, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

11-01-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 31, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Christopher Uhlar for

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-31-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 28, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-28-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 27, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-27-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 26, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
CMC TELEPHONE AMENDMENT

Dear Sir/Madam:

Sandoz Inc. hereby submits a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the October 11, 2011 and the October 12, 2011 telephone conversations between Mr. Gil Jong Kang of FDA and Ms. Bernadette Attinger of Sandoz. During these conversations, Mr. Kang requested that Sandoz update the drug substance ID test to comply with the current USP monograph and USP general chapter <197K> and provide ID test results for the USP standard and the sample using the currently approved <197K> method.

Further reference is made to the telephone deficiency letter received on October 19, 2011. A copy of the letter is provided as **Attachment-1** for ease of review. The Agency's comments are provided in bold followed by Sandoz's response in plain text.

FDA Telephone Deficiency Comments:

Please provide the following data with a brief statement on the finding.

1. **IR spectrum of the USP reference using USP <197K> method without modification.**
2. **IR spectrum of the sample using USP <197K> method without modification.**

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

3. IR spectrum of the USP reference using USP <197> method with modification.

4. IR spectrum of the sample using USP <197> with modification.

5. Superimposable IR spectra with or without modification.

In addition, please ship USP reference standard and test samples for Atorvastatin calcium along with full description of the modified USP <197> method used in your lab for the generation of IR spectrums to the following address:

James F. Allgire
Food and Drug Administration
Division of Pharmaceutical Analysis
1114 Market Street, Suite 1002
St. Louis, Missouri 63101
Tel: 314-539-3813

Sandoz's Response:

As per the Agency's request, Sandoz has performed the drug substance ID test according to the current USP general chapter <197K> using the USP reference standard. The drug substance identification test data and representative IR spectra using USP<197K> method without modification and with modification is provided on the next pages. Please find the revised drug substance specifications in **Section VIII**.

(b) (4)

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

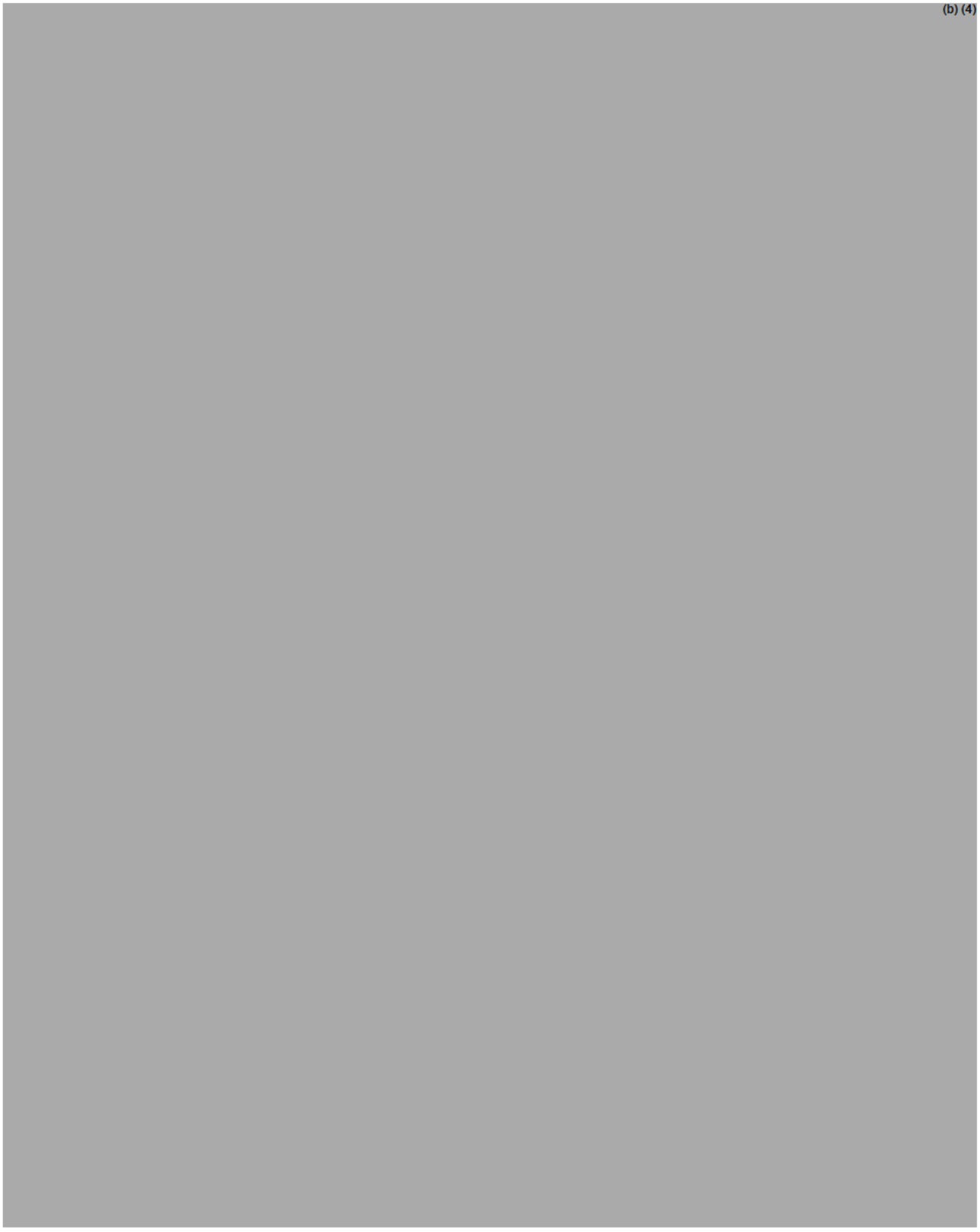
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

(b) (4)



SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This amendment is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 26, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette C

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-26-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 25, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-25-2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 24, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-24-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 21, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-21-2011
Date

Record of Telephone Conversation

Please provide the following data with a brief statement on the finding.

1. IR spectrum of the USP reference using USP <197K> method **without modification**.
2. IR spectrum of the sample using USP <197K> method **without modification**.

3. IR spectrum of the USP reference using USP <197> method **with modification**.
4. IR spectrum of the sample using USP <197> **with modification**.

5. Superimposable IR spectra with or without modification.

In addition, please ship USP reference standard and test samples for Atorvastatin calcium along with **full description of the modified USP <197> method** used in your lab for the generation of IR spectrums to the following address.

James F. Allgire
Food and Drug Administration
Division of Pharmaceutical Analysis
1114 Market Street, Suite 1002
St. Louis, Missouri 63101
Tel: 314-539-3813

Date:
October 19, 2011

ANDA Number:
077575

Product Name:
Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

Firm Name:
Sandoz Inc.

Firm Representative:
Bernadette Attinger

Phone Number:
609-627-8865

Fax Number:
609-395-2792

FDA Representative:
Gil Kang

Signatures:
GK

CC: ANDA
V:\Chemistry Division III\Team 31\ANDA REVIEWS\Gil\77575RV5_tel_IRtest.doc

---

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
10/21/2011

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 20, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-20-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 19, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-19-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 18, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-18-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 17, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-17-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 14, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-14-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 13, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette A

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-13-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 12, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-12-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 11, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

10-11-2011
Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 10, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application. Please note that permission was obtained via an October 6, 2011 e-mail from Mr. Martin Shimer, OGD, to use FedEx in lieu of the US Postal service for the purpose of providing notice to the NDA holder and any patent assignees.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-10-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 07, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-07-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 06, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-06-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 05, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-05-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 04, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

10-04-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 3, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg

CMC TELEPHONE AMENDMENT - Response to Information Request Dated September 22, 2011

Dear Sir/Madam:

Sandoz Inc. hereby submits a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the September 22, 2011 telephone conversation between Mr. Gil Jong Kang of FDA and Mr. Christopher Uhrn of Sandoz. During the conversation, Mr. Kang referenced our August 30, 2011 Telephone Amendment, specifically response #2 in which Sandoz stated that impurity (b) (4) is the same impurity as (b) (4) atorvastatin based on the same RRT and similar MS spectra. Mr. Kang questioned the slight differences in structure between the two impurities when Sandoz is considering the impurities the same. Mr. Kang also stated that if there was a mistake in our documentation that we could correct the mistake in the first annual report.

Sandoz's Response:
Please note that prior to the August 30, 2011 telephone amendment, the structure of the (b) (4) atorvastatin impurity could not be finally confirmed. However, as stated in the August 30, 2011 telephone amendment, the (b) (4) atorvastatin impurity has been prepared and its correct structure was determined and all supporting elucidation data was provided in the referenced amendment. Sandoz hereby confirms that the (b) (4) and the (b) (4) atorvastatin impurities are the same and the updated DMF section will be provided to the Agency in the first annual report.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

October 03, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette

10-03-2011

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

Date

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

September 30, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

09-30-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

September 29, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

09-29-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

September 28, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

09-28-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

September 27, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

-PATENT AMENDMENT-

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg

PATENT AMENDMENT - REVISED PATENT CERTIFICATION

Dear Sir or Madam:

Sandoz Inc. hereby submits, a "Patent Amendment" to our pending Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.95, this amendment provides for an updated patent certification with regards to the recently issued patent (8,026,376) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg. Sandoz is also concurrently complying with the requirements of 21 CFR 314.95 with respect to providing notice to the patent owner and to the holder of the approved application.

The following documents are included in this submission:

- 356h
- cover-letter
- patent certification (revised)

This correspondence is being submitted via the electronic submission gateway in eCTD format. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant: Sandoz Inc.
Address of Applicant: 506 Carnegie Center, Suite 400, Princeton, NJ 08540
RLD: Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg , 40 mg, & 80 mg Base (Pfizer's LIPITOR)

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA Amendment, is requesting approval for Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg, & 80 mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011
8,026,376	May 13, 2027	Pfizer Inc.	Nov 23, 2027

Sandoz submits the following certifications to these patents:

Paragraph III Certification For U.S. Pat. No(s). 5273995 and RE40667

Sandoz maintains its prior certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents: 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. No(s). 5686104, 5969156, and 6126971

Sandoz maintains its prior certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the claims of the following U.S. Patent(s) is/are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156, and 6126971.

With regard to U.S. Patent No(s). 5686104, 5969156, and 6126971, Sandoz has previously complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

Paragraph IV Certification For U.S. Pat. No(s). 8,026,376

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 8,026,376.

Sandoz is concurrently complying with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that there are no unexpired exclusivities associated with the above-identified RLD.

Bernadette Attinger

09-27-2011
Date

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

August 30, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –

ANDA 077575
ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
CMC TELEPHONE AMENDMENT - Response to Information Request Dated August 16, 2011

Dear Sir/Madam:

Sandoz Inc. hereby submits a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the telephone conversation between Mr. Gil Jong of FDA and Ms. Bernadette Attinger of Sandoz on August 16, 2011. In the conversation, Mr. Jong requested the sponsor to provide additional clarification to the following chemistry comments for drug substance and drug product.

FDA comments:

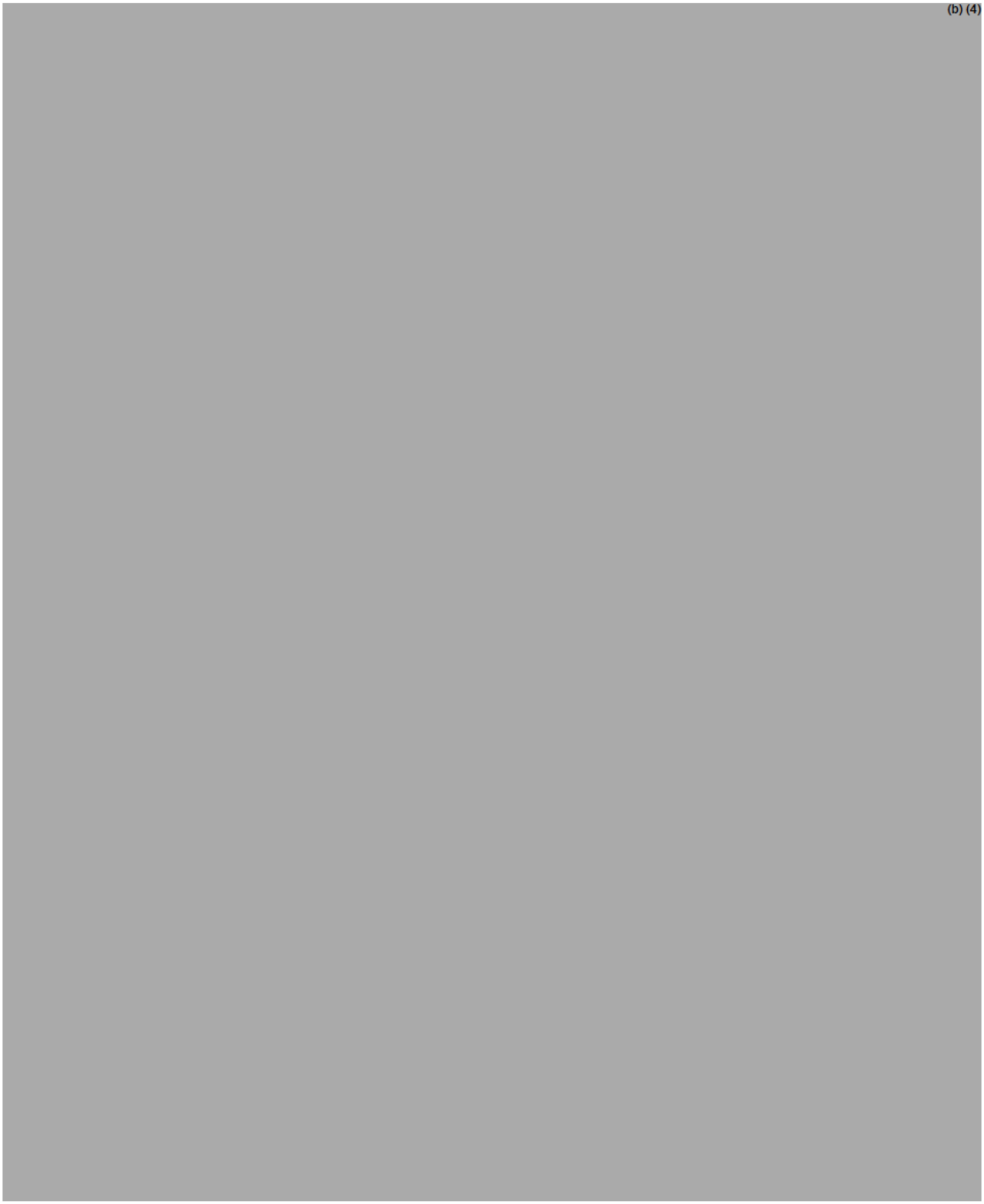
(b) (4)

[redacted]

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

(b) (4)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

August 19, 2011
ATORVASTATIN MEETING
9:00-10:30 am

Attendees:
Keith Webber
Dave Gill
Laxma Nagavelli
Haitao Li
Suhas Patankar
Bob West
Tim Ames
Robert Gaines
Leigh Ann Sears
Sivakumar Vaithiyalingam
Gil Kang
Cecilia Parise
Andre Raw
Robert Lionberger
Lawrence Yu

This group meeting was held to discuss the expedited Atorvastatin's current CMC status and their potential Tentative Approval status. The 5 ANDA's discussed were:

076477 (Ranbaxy)
077575 (Sandoz)
078773 (TEVA)
090548 (Apotex)
091226 (Mylan/Matrix)

As an action item, it was decided that since TEVA, Apotex, and Mylan ANDA's do not currently meet the USP Monograph; they will receive a communication next week to have the firm to petition USP for conversion of draft pending USP monograph to authorized USP monograph.

The possibility for in-use studies/simulated studies and comparing other in-use stability studies were discussed for the ANDA's.

At the conclusion of the meeting, it was decided more time to review the ANDA's were needed to have an answer to the ANDA statuses. A meeting will be held in 3 weeks to discuss the ANDA's cmc statuses.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LEIGH A SEARS
08/26/2011

LAXMA R NAGAVELLI
08/26/2011

SANDOZ

Bernadette Attinger
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8865 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

July 13, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –
(Response to Information Request Dated June 23, 2011)

Ref: ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. hereby submits a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the telephone conversation between Mr. Gil Jong, of FDA and William Kwok of Sandoz on June 23, 2011. In the conversation, Mr. Gil requested the sponsor to provide clarification on the proposed [redacted] (b) (4) for the drug product.

Sandoz has confirmed that the [redacted] (b) (4) for Atorvastatin Calcium Tablets [redacted] (b) (4) (b) (4) as **Attachment-2**.

Change in Official Contact Information
The new Regulatory Affairs contact person's name and contact information is provided below. This information will help facilitate future communication between the Agency and Sandoz:

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Bernadette Attinger
Director, Regulatory Affairs
Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540
Ph: (609) 627-8865
Fax: (609) 395-2792
Email: bernadette.attinger@sandoz.com

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com.

If there are any questions regarding this submission, please contact me at (609) 627-8865, via facsimile at (609) 395-2792 or by e-mail at bernadette.attinger@sandoz.com.

Sincerely,

Bernadette Attinger
Director, Regulatory Affairs

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

June 22, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –

RE: ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. is hereby submitting a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is made to the telephone deficiency comments from Mr. Gil Jong, FDA Chemistry Division to William Kwok, Sandoz dated June 21, 2011. Mr. Gil requested us additional clarification to the [redacted] (b) (4) that was submitted to the Agency dated March 11, 2009 and June 14, 2011 amendments.

Reference is also made to the labeling amendment dated May 31, 2011.

FDA Comment:

1. [redacted] (b) (4)

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

William Kwok
Director, Regulatory Affairs

Response to the Agency's telephone request dated June 21, 2011 `

The following [redacted] (b) (4) information was proposed and submitted to the Agency, amendments dated March 11, 2009 (Section XIII, pages 3-20) and June 14, 2011 (Section XIII, pages 1-19).

[redacted] (b) (4)

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

June 15, 2011

Office of Generic Drugs, HFD-600
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

– PATENT AMENDMENT –

Re: Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, and 80 mg
ANDA 077575

Dear Sir/Madam:

Reference is made to the Sandoz Inc.'s Original Abbreviated New Drug Application (ANDA) for **Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, and 80 mg** (ANDA 077575) submitted under Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Reference is also made to the Patent Certifications submitted in our original application and in our patent amendment dated June 15, 2010. In our original application, Sandoz filed a paragraph IV certification for U.S. Patent Nos. 5,686,104, 5,969,156 and 6,126,971, and a paragraph III certification for U.S. Patent Nos. 4,681,893 and 5,273,995. In our Patent Amendment dated June 15, 2010, we included a paragraph III certification for U.S. Patent No RE40667.

Reference is also made to Patent Amendment dated July 1, 2005 which we provided a statement certifying that the notice has been provided to each person identified under 21 CFR 314.95(a) and that notice met the content requirements under 314.95(c). Also, in accordance with CFR 314.95(e), we provided the documentation of receipt by the patent owner/patent holder (Pfizer, Inc and Warner-Lambert Company). Please be advised that Pfizer, Inc and Warner-Lambert Company has not filed a legal complaint against Sandoz Inc. in the requisite 45 day period.

This application contains a paragraph IV certification for U.S. Patent Nos. 5,686,104, 5,969,156 and 6,126,971, and as stated earlier, Pfizer, Inc and Warner- Lambert did not file any legal complaint against Sandoz.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Under the paragraph III certification, please note that Sandoz is eligible for a final approval for Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, and 80 mg upon expiration of the following U.S. Patents 4,681,893, 5,273,995 and RE40667. Both U.S. Patents 5273995 and RE40667 expire on June 28, 2011, and U.S. Patent 4,681,893 has been expired as of March 24, 2010.

Hence, Sandoz believe this ANDA would be eligible for a final approval on June 28, 2011.

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5i.

Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com.

Sincerely,

William Kwok
Director, Regulatory Affairs

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

June 14, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– TELEPHONE AMENDMENT –

RE: ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. is hereby submitting a "Telephone Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.96, Sandoz is responding to the FDA's telephone deficiency letter dated May 3, 2011 in which the following comments have been identified. A copy of the deficiency letter is also provided in the Attachments folder for ease of review (**FDA Letter.pdf**).

Reference is also made to the electronic communication from Ms. Sarah Nguyen, Project Manager, FDA to William Kwok, Sandoz dated May 3, 2011. Ms. Nguyen indicated that our proposed limits of (b) (4) for the drug substance and drug product are acceptable by the agency.

Reference is also made to two telephone conversations between Mr. Gil Kang, FDA and William Kwok, Sandoz on May 19, 2011 and May 23, 2011. Mr. Kang provided additional clarification on the referenced telephone deficiency letter.

FDA Comments:

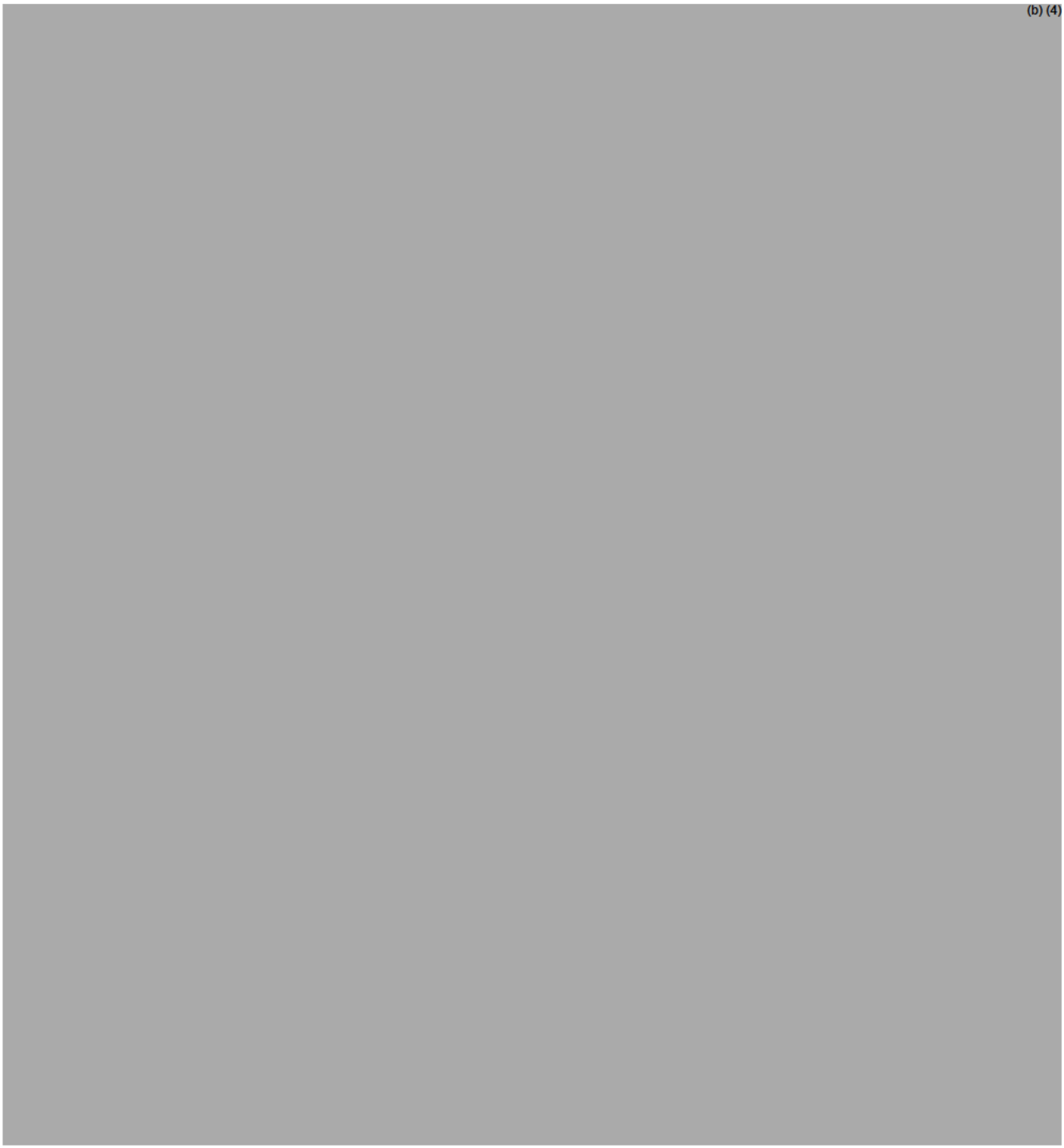
A. Deficiencies

(b) (4)

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

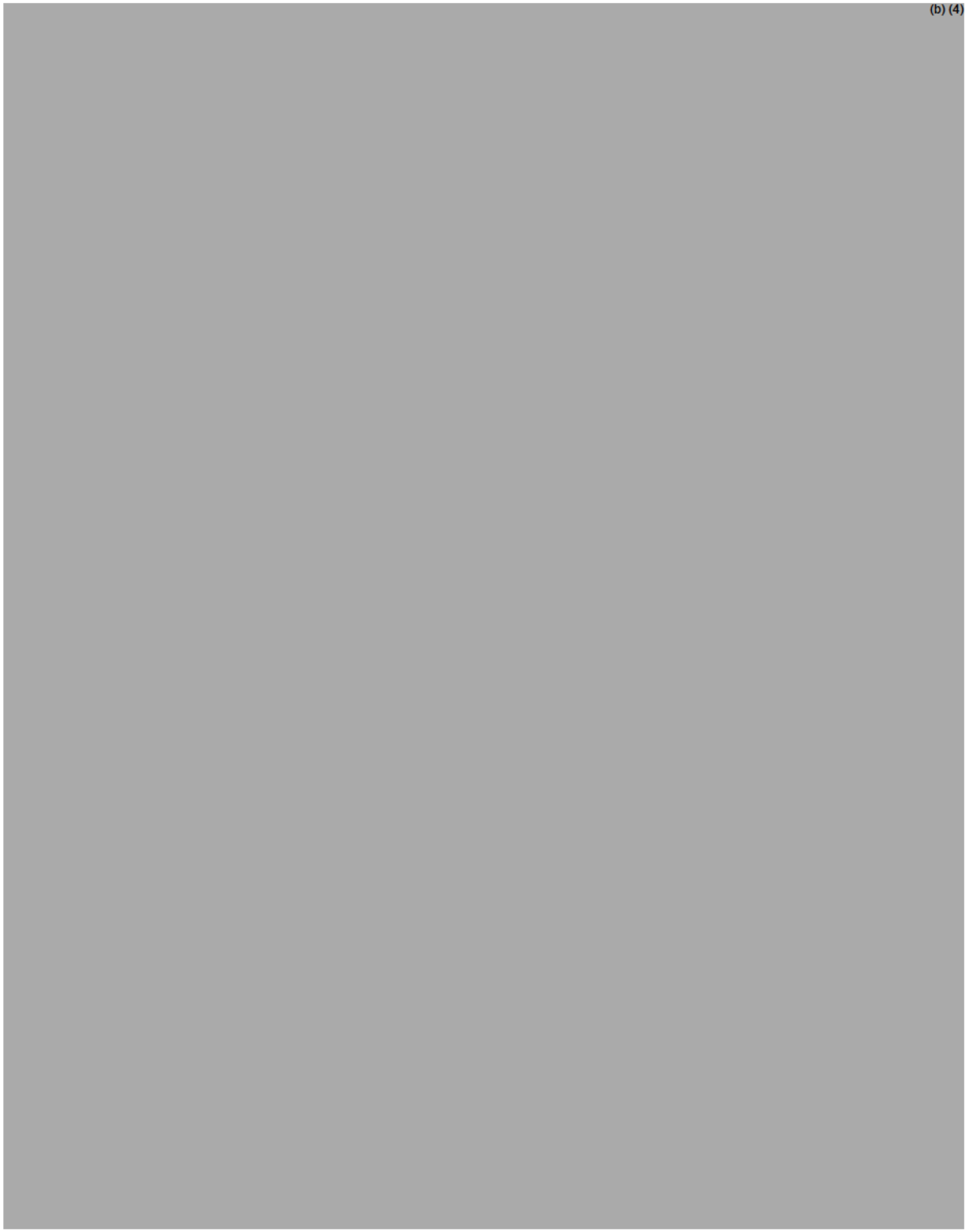
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

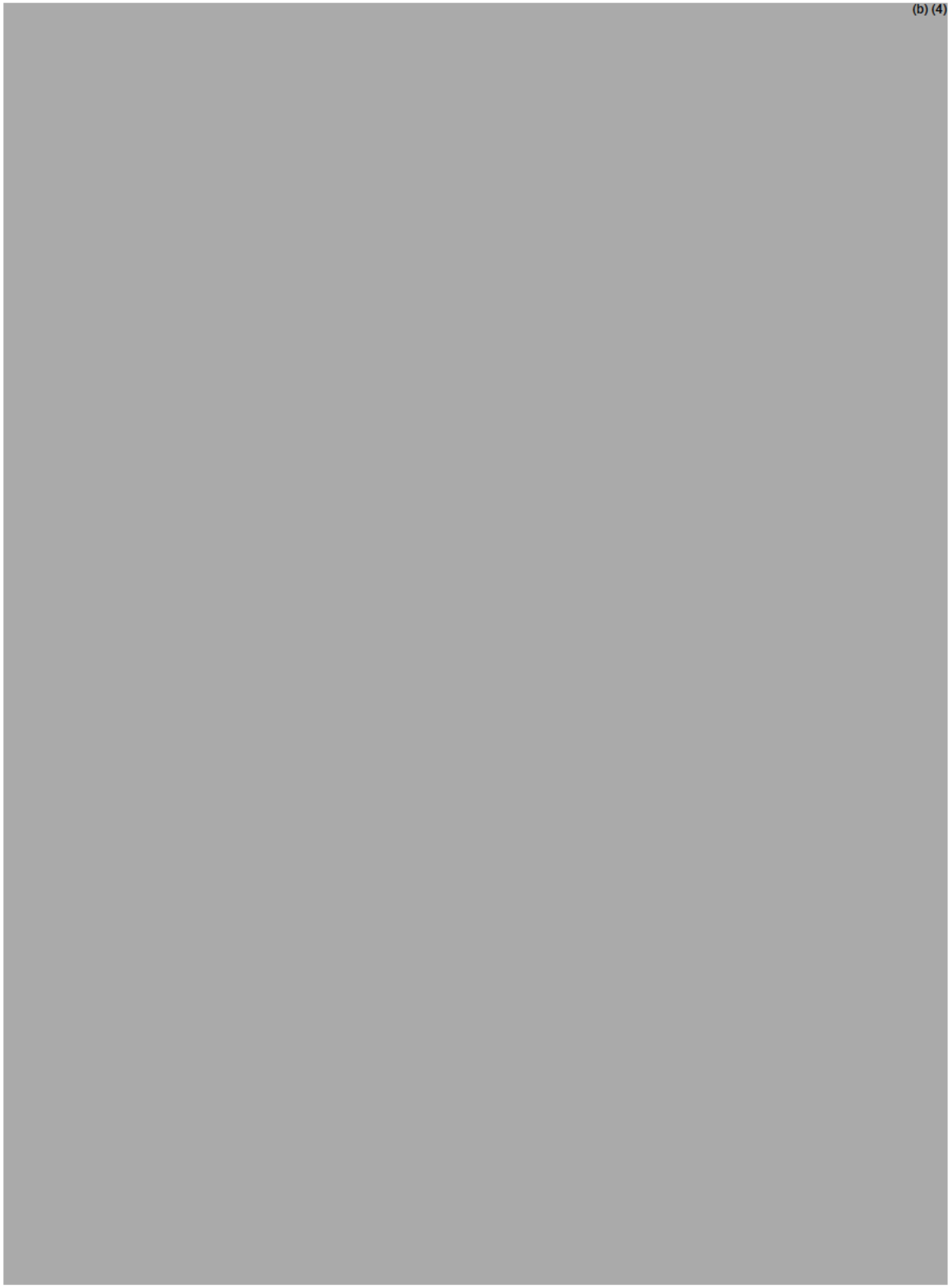
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

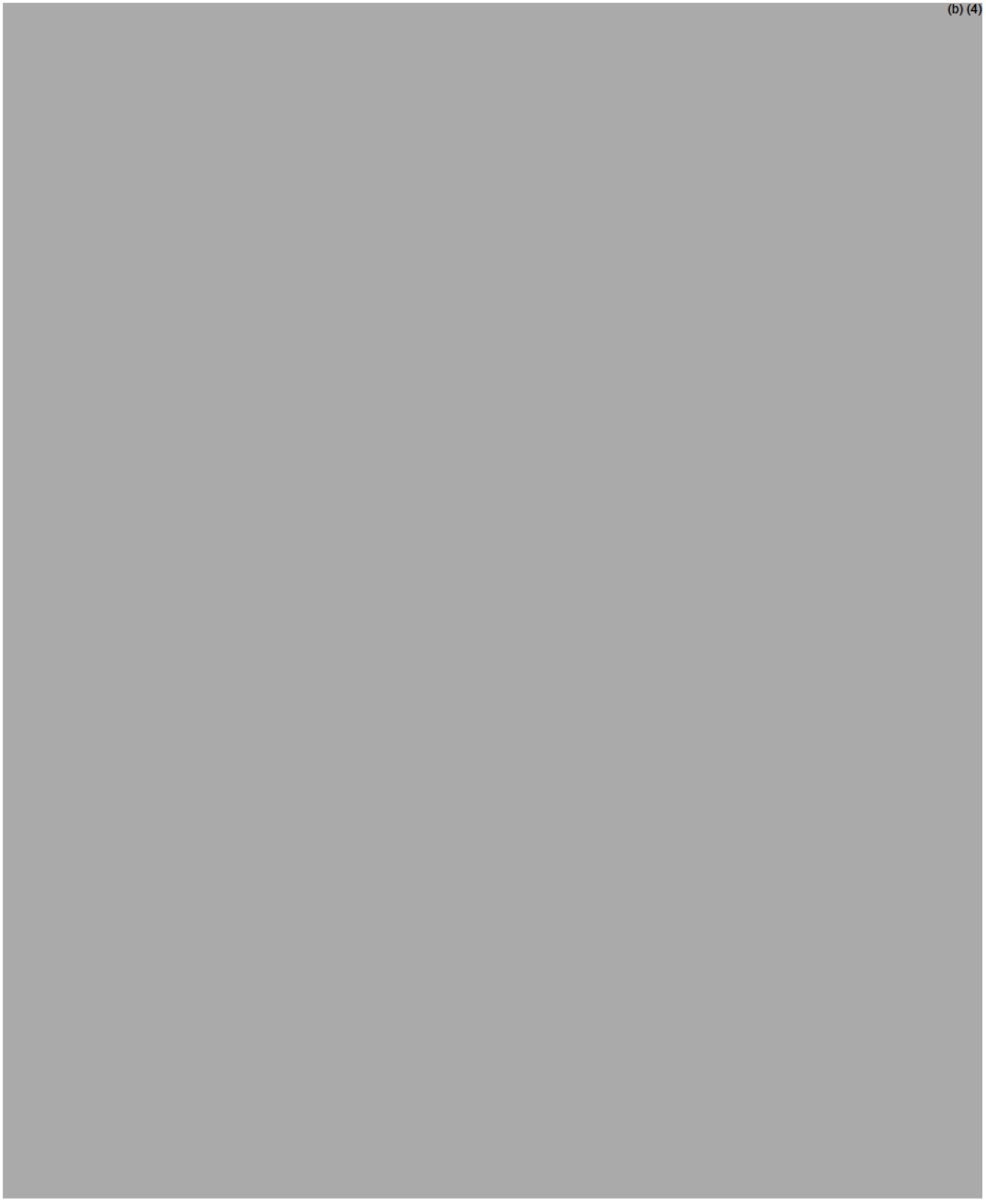
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

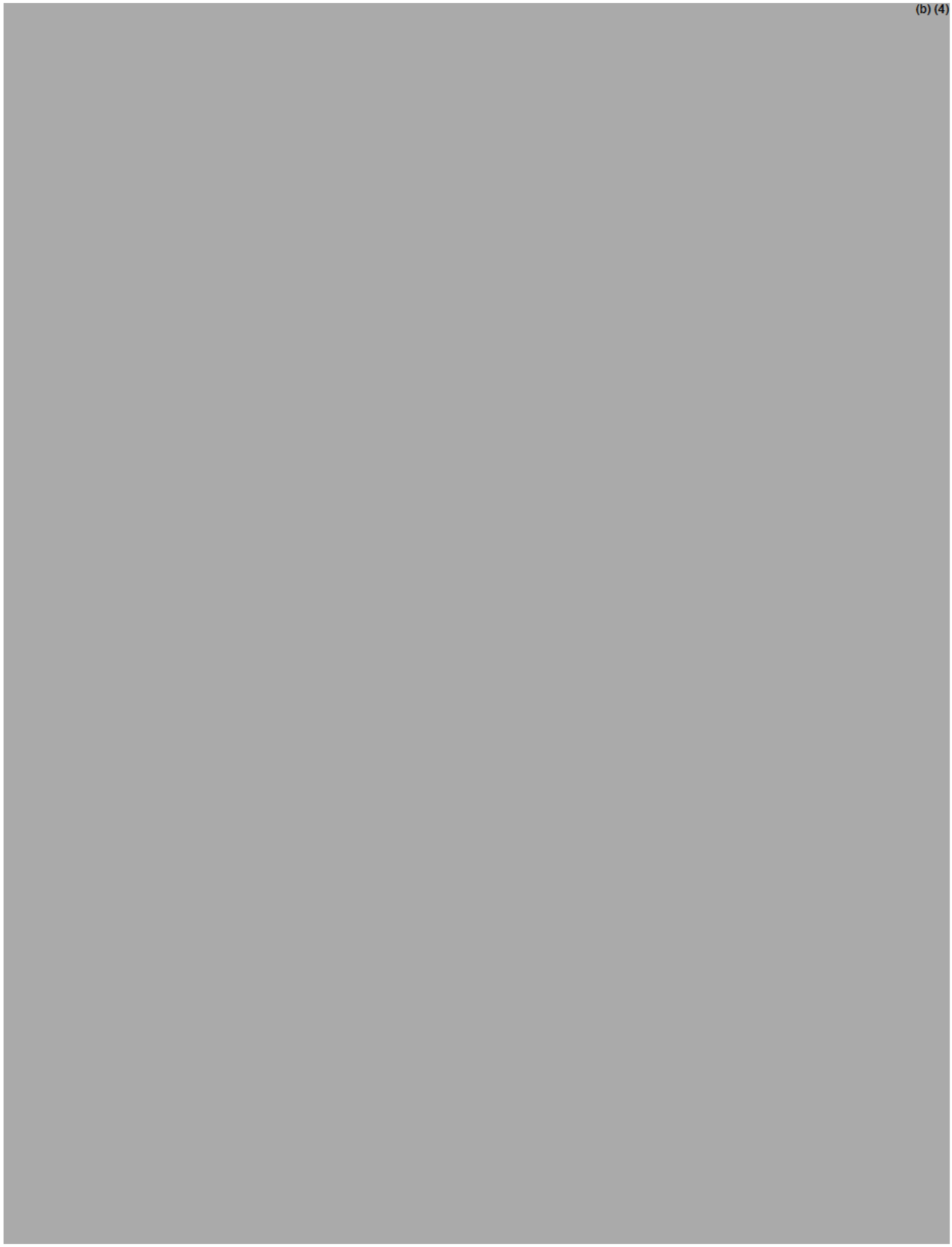
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792



The following ANDA sections were updated and provided in this amendment:

Section VIII: Active Ingredient
Section XIII: Packaging material controls
Section XI : Manufacturing and processing instructions
Section XIV: Controls for the Finished Dosage Forms
Section XV : Analytical Methods
Section XVI: Stability

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

William Kwok
Director, Regulatory Affairs

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

May 31, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– LABELING AMENDMENT –

Re: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg.
ANDA 077575

Dear Sir/Madam:

Sandoz Inc., is hereby submitting a "Labeling Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR 314.96.

In accordance with 21 CFR 314.96, Sandoz is responding to the FDA's labeling deficiency letter dated December 14, 2010. In the deficiency letter the following comments have been identified.

FDA Comments:

1. CONTAINER (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
80 mg: 30s, 90s, 100s, and 1000s tablets)

We note that you submitted container labels for 30's and 100's for all strengths. However, you did not submit pertinent chemistry such as the container/closure and stability. Please submit chemistry data to both labeling and chemistry.

Response 1:
For 30's count bottle, please note that the container closure information, packaging batch record, and stability data was provided in the "Unsolicited Amendment" dated March 11, 2009. Please refer to Section XI, Section XIII and Section XVI for the above information.

For 100's count bottle, the container closure information for all strengths is provided in this amendment, please refer to **Attachment 1** for additional details. Along with the container closure information for all strengths in 100's count, the intended Batch Packaging Records for Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg and 80 mg will be submitted as a CMC minor amendment.

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Regarding stability data for Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg and 80 mg, Sandoz submitted the 24 months stability data for all strengths of 30 counts and 3000 counts (for 10 and 20 mg), of 30 counts and 2000 counts (for 40 mg), of 30 counts and 1000 counts (for 80 mg) in the Quality Minor Amendment dated March 24, 2011. For ease of review, we have provided the same in **Attachment 2**.

Because all container sizes of HDPE bottles (for 30, 90, 100, 1000, 2000 and 3000 tablets) for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg were packaged with the same packaging material and container composition, and of the same type of closure with (b) (4) Also, the stability testing was performed on the highest and lowest packaging counts of each strength, thus a bracketing design can be applied to the intermediate packaging counts. Therefore, the stability testing of the 90's, 100's, and 1000's were omitted for 10 mg, 20 mg, and 40 mg strengths and the stability testing of the 90's and 100's were omitted for 80 mg strength.

2. (b) (4)

3.

4. INSERT
FULL PRESCRIBING INFORMATION
Revise to read:
7 DRUG INTERACTIONS
7.1 Strong Inhibitors of Cytochrome P450 3A4
Clarithromycin
Combination of Protease Inhibitors
Itraconazole

Response 4:
We acknowledge the Agency's comment, accordingly Sandoz has revised the proposed package insert labeling and provided in this submission (**proposed PI**).

5. PATIENT PACKAGE INSERT (PPI)
Please state the number of sheets you intend on providing in order for each patient to receive one.

Response 5:
In order to supply an adequate number of patient package inserts with each dispensed package, a (b) (4) will be distributed with the product

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

in the shippers. The firm plans to provide the patient package inserts for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg for each packaging count as follows:

HDPE Bottle	Number of PPI sheets (b) (4)
30's count	
90's Count	
100's count	
1000's Count	
2000's Count	
3000's Count	

The final printed stand alone Patient Package Insert (PPI) is provided in this submission (**proposed PPI**).

To facilitate review, Sandoz is also providing in this submission a side-by-side comparison of previously submitted vs. proposed package insert labeling (**comparePI**).

The following documents are included in this submission:

- 356h
- Cover Letter
- Final Printed Container Labels
- Final Printed PI and PPI (Msword & pdf)
- Packaging Material Controls (Attachment-1)
- Stability Data (Attachment-2)

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

William Kwok
Director, Regulatory Affairs

91 pages have been withheld immediately following this page as b4 (CCI/TS)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

INDRA ANTONIPILLAI

05/25/2011

Please see the internal recommendations on the pharmcology /toxicology consult on DMF-18082 (consult number 2011-0518).

KAREN L DAVIS BRUNO

05/25/2011

TELEPHONE CONFERENCE FAX

ANDA 077575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

APPLICANT: Sandoz Inc. TEL: 609-627-8854

ATTN: William Kwok FAX: 609-395-2792

FROM: Sarah Nguyen FDA CONTACT PHONE: (240) 276-8467

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated February 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

The deficiencies presented below represent TELEPHONE deficiencies identified during the ongoing review and the current review cycle will remain open. You should respond to these deficiencies with a "Telephone Amendment" within ten working days. If you have questions regarding these deficiencies please contact the Project Manager, Sarah Nguyen at (240) 276-8467. Please submit documentation by fax to the attention of the Project Manager at (240) 276-8474. Please also submit official hard copies of any faxed documentation to the Document Room.

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents will be:*

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

All ANDA documents will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

APPEARS THIS WAY ON ORIGINAL.

The deficiencies presented below represent TELEPHONE deficiencies.

A. Deficiencies:

(b) (4)

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

The safety review of (b) (4) information you have provided is pending review. After the review is completed, any deficiencies found will be communicated to you separately.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GIL JONG KANG
05/06/2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Division of Cardiovascular and Renal Products

Memorandum

Date: May 3, 2011

From: Thomas Papoian, Ph.D., D.A.B.T.
Supervisory Pharmacologist

Through: Norman Stockbridge, M.D., Ph.D.
Division Director

To: Office of Generic Drugs (OGD)

Subject: **Consult Request:**
- Subject: Follow-up Consult to the applicant's ongoing request for establishment of a maximum allowable amount of [redacted] (b) (4) As recommended in a previous Consult by this reviewer to reduce levels of [redacted] (b) (4) down to a much lower level (see review dated Aug. 18, 2010), the firm has proposed to tighten [redacted] (b) (4) from [redacted] (b) (4) ppm to [redacted] (b) (4) ppm for the drug substance and to [redacted] (b) (4) ppm for the drug product.

- Drug Product: Atorvastatin Calcium Tablets (10, 20, 40, and 80 mg).

- Applicant: Sandoz, Inc.

- Application: **ANDA #77-575.**

Reference ID: 2941809

Background

On March 10, 2006, OGD requested a Pharm/Tox consult from the Division of Metabolic and Endocrine Products (DMEP) to review proposed limits for the residual [redacted] in the drug atorvastatin calcium tablets (brand product name Lipitor®). The manufacturer and DMF holder of both the drug substance and drug product, Lek Pharmaceuticals (a Sandoz company), originally proposed a limit of [redacted] According to the currently approved product labeling, the maximum recommended human daily dose for atorvastatin is 80 mg. Levels of [redacted] would equal a daily dose of [redacted] mg.

Lek Pharmaceuticals provided a summary of toxicological information on [redacted] based on TOXNET searches from the publically available literature. The summary document used "FDA methodology" to calculate a permitted daily exposure (PDE) for [redacted]

The current Consult request from OGD asks whether the applicant's latest proposal to tighten (b) (4) ((b) (4) from (b) (4) ppm to (b) (4) ppm for the drug substance and to (b) (4) ppm for the drug product is acceptable.

Review of Additional Information Provided by the Applicant to Support the Safety of Atorvastatin Calcium Tablets with (b) (4) at (b) (4) % for Drug Substance and (b) (4) % for Drug Product

The sponsor has provided additional justification, from a (1) chemical, (2) manufacturing, and (3) toxicological perspective, for their lowered limits of (b) (4)

1. Chemical Justification

(b) (4)

2. Manufacturing Justification

(b) (4)

3. Toxicological Justification

(b) (4)

Recommendations

The latest proposed limits of [redacted] ppm for the drug substance and to [redacted] ppm for the drug product appear to be acceptable based on: (1) known toxicities following exposure to [redacted] in the workplace, (2) no significant safety issues for related [redacted] at these levels, (3) successful lowering of [redacted] limits from previously proposed levels, and (4) [redacted] for lowering levels further.

Thomas Papoian, Ph.D., D.A.B.T.
Supervisory Pharmacologist

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS PAPOIAN
05/04/2011

NORMAN L STOCKBRIDGE
05/04/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION			REQUEST FOR CONSULTATION Consult No: 2011-0517	
TO *(Division/Office)* DMEP - HFD-510 Thru: Leah Ripper, ODEII - HFD 102			FROM: Gil jong Kang	
DATE: 4/20/2011	IND NO.	ANDA NO. 077575	TYPE OF DOCUMENT Amendment	DATE OF DOCUMENT 03/24/2011,
NAME OF DRUG Atorvastatin Calcium Tablets		PRIORITY CONSIDERATION 15 days	CLASSIFICATION OF DRUG antihyperlipidemic	DESIRED COMPLETION DATE 5/5/2011

NAME OF FIRM Sandoz Inc.

REASON FOR REQUEST

I. GENERAL

Γ NEW PROTOCOL
Γ PROGRESS REPORT
Γ NEW CORRESPONDENCE
Γ DRUG ADVERTISING
Γ ADVERSE REACTION REPORT
Γ MANUFACTURING CHANGE/ADDITION
Γ MEETING PLANNED BY _____
Γ PRE NDA MEETING
Γ END OF PHASE II MEETING
Γ RESUBMISSION
Γ SAFETY/EFFICACY
Γ PAPER NDA
Γ CONTROL SUPPLEMENT
Γ RESPONSE TO DEFICPENCY LETTER
Γ FINAL PRINTED LABELING
Γ LABELING REVISION
Γ ORIGINAL NEW CORRESPONDENCE
Γ FORMULATIVE REVIEW
X *OTHER ('specify below)*

II.BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
Γ TYPE A OR B NDA REVIEW Γ END QF PHASE II MEETING Γ CONTROLLED STUDI ES Γ PROTOCOL REVIEW Γ OTHER	Γ CHEMISTRY Γ PHARMACOLOGY Γ BIOPHARMACEUTICS Γ OTHER

III.BIOPHARMACEUTICS

□ DISSOLUTION
□ PROTOCOL-- BIOPHARMACEUTICS
□ IN--VIVO WAIVER REQUEST
□ DEFICIENCY LETTER RESPONSE
□ BIOAVAILABILITY STUDIES
□ PHASE IV STUDIES

IV.DRUG EXPERIENCE

□ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
□ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
□ CASE REPORTS OF SPECIFIC *REACTIONS(List below)*
□ COMPARATIVE RISK ASSESSEMENT ON GENERIC DRUG GROUP
□ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
□ SUMMARY OF ADVERSE EXPERIENCE
POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

□ CLINICAL □ PRECLINICAL

COMMENTS
In amendment dated 3/24/11 (attached), the firm has proposed to tighten (b) (4) ((b) (4) from (b) (4) ppm to (b) (4) ppm for the drug substance and to (b) ppm for the drug product. Please review for acceptability.

The firm commits to (b) (4) once the Agency has accepted their proposed limit of (b) (4) in the drug substance, and if deemed necessary by the Agency, they will include all of the API information to the referenced ANDA.

Please cc Trang Tran, HFD-617 (Trang.Tran@fda.hhs.gov) on the review when it is being checked into DARRTS. Thank you.

SIGNATURE OF REQUESTER	METHOD OF DE LIVERY *(Check one)* □ MAIL □ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

FORM FDA 3291 (7/83)

cc: ANDA
Drug File Folder

Reference ID: 2936450

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609 627 8500 (Gen)
Fax: 609 395 2792

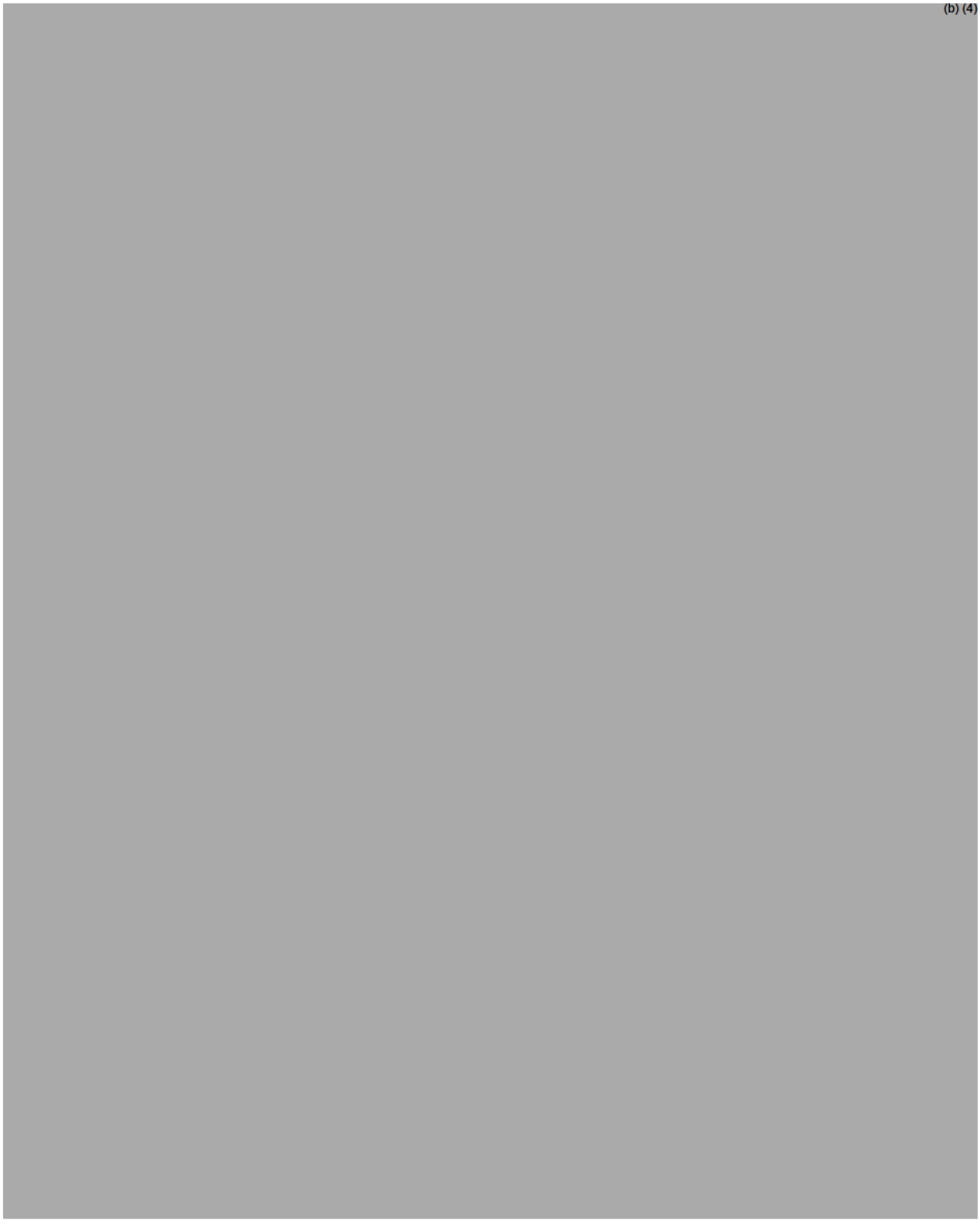
A5. Please tighten [redacted] (b) (4)

[redacted] (b) (4)

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609 627 8500 (Gen)
Fax: 609 395 2792

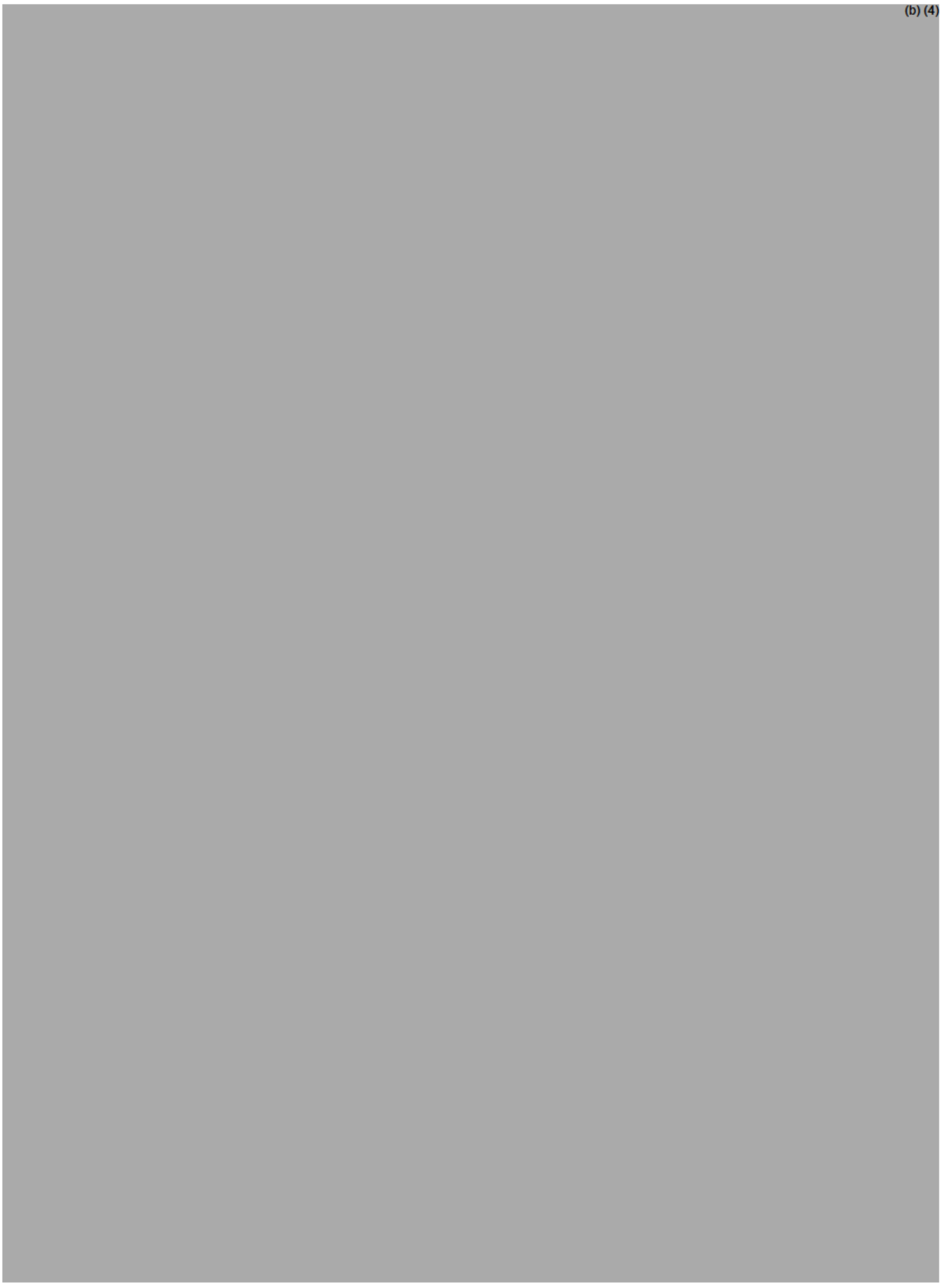
(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609 627 8500 (Gen)
Fax: 609 395 2792

(b) (4)



Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609 627 8500 (Gen)
Fax: 609 395 2792

Additionally, we would like to inform the Agency that Sandoz had two teleconferences with FDA, dated December 23, 2010 and February 8, 2011. In the meeting we discussed the outstanding issues pertaining to Part B of the CMC deficiency letter.

(b) (4)

[redacted]

The following documents were provided in this amendment:

356h form
Cover letter
Attachments folder
Section VIII: Active Ingredient
Section XIV: Controls for the Finished Dosage Forms
Section XV: Analytical Methods
Section XVI: Stability

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

Nama Vamsi

Digitally signed by Nama Vamsi
DN: cn: Nama Vamsi, ou: pwp e GX, serialNumber: 998755, dc: com, novartis
Reason: for William Kwok. I agree to the terms defined by the placement of my signature on this document
Date: 2011.03.24 15:34:19 -04'00'

William Kwok
Director, Regulatory Affairs

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SARAH K NGUYEN
04/21/2011

TRANG Q TRAN
04/21/2011

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: April 8, 2011

FROM: Robert L. West, Deputy Director
Office of Generic Drugs

THROUGH: Keith O. Webber, Ph.D., Deputy Director
Office of Pharmaceutical Science

SUBJECT: Expedited Review of Certain Atorvastatin ANDAs

TO: ANDA 077575 - Sandoz Inc.; ANDA 078773 - Teva Pharmaceuticals USA; ANDA 090548 - Apotex Inc.; ANDA 091226 - Matrix Laboratories/Mylan Pharmaceuticals

THIS DOCUMENT CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION

Pfizer's Lipitor (atorvastatin calcium) is a cholesterol-lowering agent that has been very widely prescribed for many years. The purpose of this memorandum is to document the agency's basis for expediting the review of certain atorvastatin ANDAs.[1] The actual decision to expedite the review of eligible atorvastatin ANDAs was made in late February 2011; reviewers were notified of this decision at that time.

Ranbaxy submitted its atorvastatin ANDA in 2002. It was the first generic applicant to submit an ANDA for atorvastatin. Ranbaxy challenged all the patents listed by Pfizer as covering Lipitor. By challenging the patents, under the FD&C Act Ranbaxy became eligible for 180 days of generic drug exclusivity. As a pre-MMA ANDA, the Ranbaxy ANDA is not subject to the forfeiture provisions now found in the 180-day exclusivity provisions of the Act.

[1] It is acknowledged that the circumstances here do not fit squarely under OGD's MaPP 5240.3, which among other things describes circumstances under which an ANDA will be given expedited review. However, the circumstances here (e.g., the existence and complexity of the questions related to the Ranbaxy AIP and ANDA reliability, the highly uncertain date upon which ANDAs may be eligible for final approval, the review issues posed by the applications, and the size of the market demand for this drug product) are of such an unusual nature that they could not have been anticipated. Review of these applications on an expedited basis is, however, consistent with OGD's long-term goal of reviewing pending ANDAs in such a manner that, by the time patent and exclusivity barriers to approval have expired, appropriate reviews will have been completed. With first generic ANDAs that have been found scientifically approvable, OGD has a long history of approving these as promptly as permitted under the statutory provisions pertaining to patents, patent litigation, and exclusivity. Prompt review of ANDAs does not, of course, guarantee that any application will be ready for final approval as of a specific date. To be approved, an application must meet the requirements under section 505(j) of the FD&C Act and applicable regulations.

In a letter dated February 25, 2009, CDER informed Ranbaxy that CDER was applying its Application Integrity Policy (AIP) to the applications CDER identified as originating from Ranbaxy's Paonta Sahib site in India. CDER concluded that there was:

> "a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise significant questions regarding the reliability of the data and information contained in applications … developed at the Ranbaxy Laboratories, Paonta Sahib site."

Certain "subsequent applicants" (i.e., those applicants whose ANDAs would not be approved prior to or during Ranbaxy's 180-day exclusivity period) have written the agency and stated that the agency should declare Ranbaxy ineligible for 180-day exclusivity (in short, because of the AIP). Mylan recently brought suit against the agency on this point. No decision has been made, at this time, about the status of Ranbaxy's eligibility for 180-day exclusivity. Issues related to Ranbaxy's eligibility for exclusivity and the review of the Ranbaxy ANDA are not addressed in this memorandum.

November 30, 2011, is the earliest date Ranbaxy could market under its 2008 settlement agreement with Pfizer. If Ranbaxy were to obtain approval of its ANDA and market promptly after that date, approval of subsequent ANDAs could be blocked until the end of May, 2012. [2] However, June 28, 2011, is the expiration date of the pediatric exclusivities attaching to two key Lipitor patents. If Ranbaxy loses its eligibility for 180-day exclusivity, the ANDAs identified in this memorandum could become eligible for approval on June 28, 2011.[3]

In managing the workload in OGD, we must take into account these unusual circumstances and the possibility that Ranbaxy may lose its claim for exclusivity either by relinquishing it or by an agency determination that Ranbaxy is not eligible for exclusivity, e.g., because Ranbaxy's ANDA was not "substantially complete" at the time of its submission. If this were to happen, the agency has concluded that it is in the public interest to have completed its scientific reviews of any atorvastatin ANDA that otherwise could be approved and marketed to the American public as early as June 28, 2011. To date, no atorvastatin ANDA has been tentatively approved.

---

[2] On March 23, 2011, counsel for Ranbaxy notified FDA that if it does not receive final approval by March 1, 2012, Ranbaxy will not object to FDA's approval of any other ANDA for atorvastatin after May 30, 2012 (i.e., the approximate date upon which Ranbaxy's exclusivity would expire if it began commercial marketing promptly after an approval on November 30, 2011). Ranbaxy's representations diminish significantly, but do not completely eliminate, the possibility that its eligibility for exclusivity could result in an indefinite delay in approval of generic Lipitor. Among other things, Ranbaxy could attempt to withdraw the commitment made in the letter.

[3] There is one applicant as to whom there may be no patent barrier to approval as early as May 2011. However, that applicant currently has significant deficiencies in its application, so it is not likely to be technically approvable by that date.

Reference ID: 2930036

OGD has identified[4] those ANDAs that meet the following criteria:

- patent litigation has been settled and there has been a representation by the ANDA applicant that the settlement will permit approval as early as June 28, 2011;
- the applicant was not sued (so there is no 30-month stay of approval to consider); or
- the relevant 30-month stays will have expired before June 28, 2011.

Sandoz's ANDA 077575, Teva's ANDA 078773, Apotex's ANDA 090548, and Matrix/Mylan's ANDA 091226 currently meet one or more of these criteria, and have been designated for expedited review. OGD's process for review is intended to permit the approval of generic atorvastatin as soon as applicable scientific, regulatory, and legal requirements have been met.

[4] Identification was based on documents submitted by ANDA sponsors and available court documents. It should be noted that, of the ANDAs the reviews of which are *not* being expedited, all were sued on the '156 patent and the earliest 30-month stay does not expire until April 27, 2012. In addition, there is one ANDA that was submitted so recently (acknowledged for receipt on March 21, 2011) that litigation information is not yet available.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

PATRICIA L DOWNS
04/08/2011

ROBERT L WEST
04/08/2011
Deputy Director
Office of Generic Drugs

KEITH O WEBBER
04/08/2011

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 24, 2011

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20855

– MINOR AMENDMENT –
(Quality Minor Amendment/Response to Information Request)

RE: ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. is hereby submitting a "Minor Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

In accordance with 21 CFR 314.96, Sandoz is responding to the FDA's deficiency letter dated September 28, 2010 in which the following comments have been identified. A copy of the deficiency letter is also provided in the Attachments folder for ease of review (**FDA Letter.pdf**).

FDA Comments:

(b) (4)

13 pages have been withheld as b4 (CCI/TS) immediately following this page

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Additionally, we would like to inform the Agency that Sandoz had two teleconferences with FDA, dated December 23, 2010 and February 8, 2011. In the meeting we discussed the outstanding issues pertaining to Part B of the CMC deficiency letter.

(b) (4)

[redacted]

The following documents were provided in this amendment:

356h form
Cover letter
Attachments folder
Section VIII: Active Ingredient
Section XIV: Controls for the Finished Dosage Forms
Section XV: Analytical Methods
Section XVI: Stability

This correspondence is being submitted via the electronic submission gateway. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

This document contains trade secrets and/or confidential commercial information and is therefore exempt from disclosure under the Freedom of Information Act and FDA implementing regulations.

For all technical issues, including submission through the gateway, please contact Sandoz Inc. at e.sub@sandoz.com.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

William Kwok
Director, Regulatory Affairs

OFFICE OF GENERIC DRUGS EXPEDITED REVIEW REQUESTED

ANDA#/SUPPLEMENT#: 077575 APPLICANT: Sandoz Inc.
DRUG: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg DATE OF SUBMISSION: March 14, 2011

The Office of Generic Drugs may grant expedited review status to either an Original or Supplemental abbreviated new drug application for the following reasons (MaPP 5240.1,& MaPP 5240.3). At least one of the criteria must be met to receive Expedited Review Status:

1. PUBLIC HEALTH NEED. Events that affect the availability of a drug for which there is no alternative

2. EXTRAORDINARY HARDSHIP ON THE APPLICANT.

   a) Catastrophic events such as explosion, fire storms damage.

   b) Events that could not have been reasonably foreseen and for which the applicant could not plan. Examples include:

      - Abrupt discontinuation of supply of active ingredient, packaging material, or container closure; and
      - Relocation of a facility or change in an existing facility because of a catastrophic event (see item 2.a)

3. AGENCY NEED.
   a) Matters regarding the government's drug purchase program, upon request from the appropriate FDA office.
   b) Federal or state legal/regulatory actions, including mandated formation changes or labeling changes if it is in the Agency's best interest.
   c) Expiration-date extension or packaging change when the drug product is the subject of a government contract award.
   d) Request for approval of a strength that was previously tentatively approved (To be used in those cases where 180-day generic drug exclusivity prevented full approval of all strengths).
   e) MaPP 5240.3 conditions.

RECOMMENDATIONS:

DISCIPLINE	STATUS	SIGNATURE/DATE
Team Project Manager (PM must Endorse)	Grant☒ Deny☐	L.Sears/3/14/2011
Chemistry Team Leader (sign as needed)	Grant☒ Deny☐	L.Nagavelli/3/15/2011
Micro Team Leader (sign as needed)	Grant☐ Deny☐	
Labeling Team Leader (sign as needed)	Grant☐ Deny☐	
Chem. Div./Deputy Director (DO must Endorse)	Grant☐ Deny☐	
Office Director/Deputy Director (email concurrence) (Original ANDAs)	Grant☒ Deny☐	Bob West (email below)

RETURN TO PROJECT MANAGER CHEMISTRY TEAM: Team 34
a) When expedited review is denied, notify the applicant by telephone

ENTER FORM INTO DARRTS DATE 3/14/2011
Paste Email Copy Below:

Reference ID: 2918275

From: West, Robert L
Sent: Friday, March 11, 2011 11:08 AM
To: Sears, Leigh Ann; Vu, Thuyanh (Ann); Gaines, Robert; Chun, Nam
Cc: Sayeed, Vilayat A; Gill, Devinder; Vaithiyalingam, Sivakumar; Patankar, Suhas; Hassall, Rita R; Webber, Keith; Read, David T; Ames, Timothy W; Rickman, William P; Yu, Lawrence; Shimer, Martin; Golson, Lillie D; Grace, John F; Lee, Koung U; Nagavelli, Laxma
Subject: EXPEDITED REVIEW GRANTED FOR ANDA'S 77-575 (SANDOZ) AND 90-548 (APOTEX) FOR ATORVASTATIN CALCIUM TABLETS - CONFIDENTIAL
Atorvastatin Teams:

Please refer to my email dated February 17, 2011, in which I noted that the Office had granted "expedited review" status to Teva's ANDA 78-773 and to Matrix/Mylan's ANDA 91-226 for Atorvastatin Calcium Tablets.

At this time, we are also granting "expedited review" status to the following ANDAs for Atorvastatin Calcium Tablets:

ANDA 90-548 Apotex CMC Team 33 Bio complete and acceptable.

ANDA 77-575 Sandoz CMC Team 34 Bio complete and acceptable.

We, along with CDER's Office of Chief Counsel, have determined that both Apotex and Sandoz could become eligible for final approval about the same time as Teva and Matrix/Mylan, but for different reasons (expiration of 30-month statutory hold period v. settlement agreements with the NDA holder).

Thus, as an issue of fairness to the applicants and out of concern that the office needs to anticipate all options with respect to its review of this drug product, "expedited review" status is granted to Apotex and Sandoz for their Atorvastatin Calcium Tablet ANDA.

Bob/Leigh Ann: Please make certain that the proper entries are made in DARRTS for both the Apotex and Sandoz applications to reflect the "expedited review" status and notify Office of Compliance of their priority status.

Thank you for your cooperation,

Bob

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LEIGH A SEARS
03/15/2011

LABELING COMMENTS

ANDA 77575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North I
7520 Standish Place
Rockville, MD 20855-2773
240-276-8991
Thuyanh.vu@fda.hhs.gov

TO: Sandoz Inc. TEL: 609-627-8854

ATTN: William Kwok FAX: 609-395-2792

FROM: Ann Vu

This facsimile is in reference to your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg.

Pages (including cover): 4

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents has become:*

Office of Generic Drugs
Document Control Room
7620 Standish Place
Rockville, Maryland 20855

ANDAs will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 77575 Date of Submission: November 22, 2010

Applicant's Name: Sandoz Inc.

Established Name: Atorvastatin Calcium tablets 10 mg , 20 mg, 40 mg, 80 mg

---

Labeling Deficiencies:

1. CONTAINER (10 mg and 20 mg: 30s, 90s, 100s, 1000s and 3000 tablets
   40 mg: 30s, 90s, 100s, 1000s and 2000 tablets
   80 mg: 30s, 90s, 100s, and 1000s tablets)

   We note that you submitted container labels for 30s and 100s for all strengths. However, you did not submit pertinent chemistry information such as the container/closure and stability. Please submit chemistry data to both labeling and chemistry.

2. (b) (4)

3.

   Acceptable in final print.

4. INSERT

   FULL PRESCRIBING INFORMATION: CONTENTS*

   Revise to read:

   7 DRUG INTERACTIONS

   7.1 Strong Inhibitors of Cytochrome P450 3A4
   Clarithromycin
   Combination of Protease Inhibitors
   Itraconazole

5. PATIENT PACKAGE INSERT (PPI)

   Please state the number of sheets you intend on providing in order for each patient to receive one.

Submit labeling electronically.

Prior to approval, it may be necessary to revise your labeling subsequent to approved changes for the reference listed drug. In order to keep ANDA labeling current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address - http://service.govdelivery.com/service/subscribe.html?code=USFDA_17

To facilitate review of your next submission please provide a side-by-side comparison of your proposed labeling with your last labeling submission with all differences annotated and explained.

{See appended electronic signature page}

_____
Wm. Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOHN F GRACE
12/13/2010
for Wm Peter Rickman

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

November 22, 2010

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
7620 Standish Place
Rockville, MD 20857

– LABELING AMENDMENT –

Re: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. is hereby submitting a "Labeling Amendment" to our pending Abbreviated New Drug Application, Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg, ANDA 077575 as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR 314.96.

In this amendment Sandoz is submitting the following updated labeling for Agency review.

1. **Package Insert and PPI**
   Revised Package Insert (PI) and Patient Information Leaflet (PIL) labeling as per the RLD labeling updates dated 06/17/2009.

2. **Container and** (b) (4) **Labeling**

   (a) Container Labeling
   The following Agency previously approved container labels will be revised with Sandoz NDC numbers.

   10 mg: Bottles of 90, 1000 and 3000 tablets
   20 mg: Bottles of 90, 1000 and 3000 tablets
   40 mg: Bottles of 90, 1000 and 2000 tablets
   80 mg: Bottles of 90 and 1000 tablets

   In addition to the above counts, Sandoz is also proposing the following new counts container labeling for Agency review.

   10 mg: Bottles of 30 and 100 tablets
   20 mg: Bottles of 30 and 100 tablets

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

40 mg: Bottles of 30 and 100 tablets
80 mg: Bottles of 30 and 100 tablets

(b) (4)

To facilitate review, Sandoz is also providing in this submission a side-by-side comparison of container (previously approved vs. proposed), (b) (4) and package insert labeling (RLD vs. Proposed).

The following documents are included in this submission:

- 356h
- Cover Letter
- Labeling

This correspondence is being submitted via the electronic submission gateway. The size of submission is approximately 12 MB. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*.

Please note that a letter of non-repudiation agreement was submitted by Sandoz on November 30, 2007.

For all technical issues, including submission through the gateway and or the eCTD organization, please contact Sandoz Inc. at e.sub@sandoz.com."

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

William Kwok
Director, Regulatory Affairs

QUALITY DEFICIENCY - MINOR

ANDA 077575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

APPLICANT: Sandoz Inc. TEL: 609-627-8854

ATTN: William Kwok FAX: 609-395-2792

FROM: Sarah Nguyen FDA CONTACT PHONE: (240) 276-8467

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated February 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to your amendment dated September 26, 2007.

The Division of Chemistry has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached **3** pages. This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

Your amendment should respond to all of the deficiencies listed. **Facsimiles or partial replies will not be considered for review**, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. Your cover letter should clearly indicate that the response is a ***QUALITY MINOR AMENDMENT / RESPONSE TO INFORMATION REQUEST*** and should appear prominently in your cover letter.

We also request that you include a copy of this communication with your response. Please direct any questions concerning this communication to the project manager identified above.

SPECIAL INSTRUCTIONS:

*Effective **01-Aug-2010**, the new mailing address for Abbreviated New Drug Application (ANDA) Regulatory Documents will be:*

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North VII
7620 Standish Place
Rockville, Maryland 20855

All ANDA documents will only be accepted at the new mailing address listed above. For further information, please refer to the following websites prior to submitting your ANDA Regulatory documents: Office of Generic Drugs (OGD): http://www.fda.gov/cder/ogd or Federal Register: http://www.gpoaccess.gov/fr/

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 077575

APPLICANT: Sandoz Inc.

DRUG PRODUCT: Atorvastatin Tablets 10 mg, 20 mg, 40 mg, and 80 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

(b) (4)

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

(b) (4)

(b) (4)



Sincerely yours,

{See appended electronic signature page}

Vilayat A. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHING HOU H LIU
09/27/2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Division of Cardiovascular and Renal Products

Memorandum

Date: August 18, 2010

From: Thomas Papoian, Ph.D., D.A.B.T.
Pharmacologist

Through: Albert DeFelice, Ph.D.
Supervisory Pharmacologist

Through: Norman Stockbridge, M.D., Ph.D.
Division Director

To: Office of Generic Drugs (OGD)

Subject: **Consult Request:**
- Subject: Request for establishment of a maximum allowable amount of (b) (4)

- Drug Product: Atorvastatin Calcium Tablets (10, 20, 40, and 80 mg).

- Applicant: Sandoz, Inc.

- Application: **ANDA #77-575.**

Background

On March 10, 2006, OGD requested a Pharm/Tox consult from the Division of Metabolic and Endocrine Products (DMEP) to review proposed limits for the residual [redacted] in the drug Atorvastatin Calcium Tablets (brand product name Lipitor®). The manufacturer and DMF holder of both the drug substance and drug product, Lek Pharmaceuticals (a Sandoz company), originally proposed a limit of [redacted] According to the currently approved product labeling, the maximum recommended human daily dose for atorvastatin is 80 mg. Levels of [redacted] at [redacted] would equal a daily dose of [redacted] mg.

Lek Pharmaceuticals provided a summary of toxicological information on [redacted] based on TOXNET searches from the publically available literature. The summary document used "FDA methodology" to calculate a permitted daily exposure (PDE) for [redacted]

(b) (4)

Conclusions

Since a safe level or maximum daily allowable amount of (b) (4) could not be determined, the following can again be concluded:

Although existing animal and human safety data for (b) (4) ((b) (4) show relatively low toxicity after oral, dermal, or respiratory exposures, ingestion of any (b) (4) (b) (4) is not without risks, particularly when the relatively high levels of (b) (4)

Recommendations

Recommendation for the current applicant, similar to that stated previously, are as follows:

(b) (4)

Thomas Papoian, Ph.D., D.A.B.T.
Pharmacologist

References

Atorvastatin Calcium (Lipitor®) Product Labeling; NDA #20-702; 6/17/2009; http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf.

Guidance for Industry: Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches; Draft; Dec. 2008; URL: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079235.pdf.

(b) (4)

Guidance for Industry: ICH-Q3C — Tables and List; Nov. 2003 (Revision 1); URL: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073395.pdf.

Attachment - 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Division of Cardiovascular and Renal Products

Memorandum

Date: August 10, 2010

From: Thomas Papoian, Ph.D., D.A.B.T.
Pharmacologist

Through: Albert DeFelice, Ph.D.
Supervisory Pharmacologist

Through: Norman Stockbridge, M.D., Ph.D.
Division Director

To: Office of Generic Drugs (OGD)

Subject: **Consult Request:**
- Subject: Toxicology review of the (b) (4) at the proposed level of (b) (4)

- Drug Product: (b) (4)

- Applicant: (b) (4)

- Application: (b) (4)

4 pages have been withheld immediately following this page as b4 (CCI/TS)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	SANDOZ INC	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS PAPOIAN
08/18/2010

ALBERT F DEFELICE
09/01/2010

NORMAN L STOCKBRIDGE
09/01/2010

Signed off in DARRTS on 8/25/10

2.6 PHARMACOLOGY/TOXICOLOGY REVIEW

2.6.1 INTRODUCTION AND DRUG HISTORY

ANDA number: ANDA 77-575
Drug Names: Atorvastatin Calcium (RLD Lipitor), 10, 20, 40 mg.

Consult #: 2010-0442 for atorvastatin calcium tablets.

Consult from: Gil Jong Kang. Request date: 8/10/10.
Desired completion date: 8/25/2010

Date of submission: 3/13/2006 submission.

Generic drug name: Atorvastatin calcium tablets from Sandoz Inc. The reference listed drug is Lipitor tablets from Pfizer.

Drug class: Statins.

Category: Lipid altering, hypolipidemic.

Subject of Consult: In the current consult, OGD has requested a pharmacology/toxicology consult on the qualification of (b) (4) in atorvastatin calcium for ANDA 75575. Previously (3/10/06) a pharmacology/toxicity consult was requested for (b) (4) limit of (b) (4) ppm under the DMF 18082 (Lek's Pharmaceuticals atorvastatin calcium). Lek supposedly manufactures both the drug substance and the drug product. OGD states that the consult review completed on 3/13/06 (on DMF 18082) does not specify the allowable amount of (b) (4). The current consult states that in the amendment, Lek has tightened the limit of (b) (4) to NMT (b) (4) ppm in their atorvastatin drug product. They want us to establish the maximum allowable amount of (b) (4) for atorvastatin calcium tablets since this is a drug for chronic use. See the comments below.

> Please request a Pharm/Tox consult on Lek's report of "Qualification of (b) (4) in Atorvastatin Calcium" for ANDA 077575. In the amendment, Lek has tightened the limit for (b) (4) to NMT (b) (4) ppm from (b) (4) ppm based on their toxicological report. Previously a Pharm/Tox consult was requested on (b) (4) for DMF18082 (Lek's Atorvastatin Calcium. Please note Lek manufactures both the drug substance and drug product). However, the consult result on 13-MAR-2006 (attached file) did not specify the allowable amount of (b) (4). Please ask Pharm/Tox reviewer to establish the maximum allowable amount of (b) (4) for Atorvastatin Calcium Tablets as this is a long term use drug.

Reviewer name: Indra Antonipillai, Ph.D. Pharmacology Reviewer.
Division: Division of Metabolic and Endocrinology products.

Review completion date: 8/24/10

Introduction and drug history: On 3/16/2006 a Pharmacology/toxicity consult was completed on DMF 018082 (sponsor: Lek pharmaceuticals, Slovenia, it is now a Sandoz drug), in which the consult was requested to review the proposed residual limit of (b) (4) ppm of (b) (4) (or (b) (4) mg/m^2) for atorvastatin calcium. The sponsor Lek Pharmaceuticals had provided summary of toxicity studies on (b) (4) from Toxnet Searches, based on CAS # 108-20-3

The maximum allowable limit of (b) (4) ppm or (b) (4) of (b) (4) in the maximal recommended human dose (MRHD) of 80 mg/day atorvastatin would be (b) (4) mg/m^2). Lek Pharmaceuticals has now tightened the limit of (b) (4) to NMT (b) (4) ppm in their drug product, and they state that the maximum limit of (b) (4) in the maximal recommended human dose (MRHD) of 80 mg/day atorvastatin would be (b) (4)

Lek has provided following information on [(b) (4)]

Human Exposure

The NIOSH recommended exposure limit is an average of [(b) (4)] over a 10-hour period[26]. As noted above human exposure to [(b) (4)] ppm for 15 minutes did not cause any irritation; however, exposure to [(b) (4)] ppm for 5 minutes was irritating to the eyes and nose. At a concentration of [(b) (4)] ppm, some subjects considered the odor unpleasant. Humans are exposed to [(b) (4)] when handling [(b) (4)] The highest expected exposure to humans is in work areas where [(b) (4)] is manufactured and used.

Sponsor briefly describes (see below the hazard summary) that the NOAEL of [(b) (4)] from a subchronic 3-month inhalation study in rats is [(b) (4)] ppm. They also use NOAEL of <250 mg/kg/day from an oral carcinogenicity study in rats (but this dose they state produces lymphoreticular tumors in rats). Note that both above studies are inadequate, as the first study was an inhalation study (while the current drug atorvastatin will be administered orally to patients, and it is for a chronic use). The second carcinogenicity study, does not establish a NOAEL, as lymphoreticular tumors were observed at the lowest dose of 250 mg/kg/day in rats.

Discussion of Hazard (Non-Clinical and Clinical Safety) and Assessment of Risk

Hazard Summary

[(b) (4)] is rapidly absorbed from the lungs or gastrointestinal tract through the blood. The oral LD_{50} values for [(b) (4)] in rats and rabbits are high [(b) (4)] g/kg). [(b) (4)] is irritating to the eyes and is a mild skin irritant causing dermatitis after repeated exposures.

In subchronic rat studies, the lowest NOAEL was [(b) (4)] ppm by the inhalation route. At the next highest dose level [(b) (4)] ppm), increased liver and kidney weights, hepatocellular hypertrophy, and hyaline droplet formation in the convoluted tubules were observed. Sperm parameters were examined in one of the subchronic toxicity studies and no effects were observed at dose levels up to [(b) (4)] ppm.

In a lifetime oral (gavage in [(b) (4)] carcinogenicity study, [(b) (4)] exposure to rats resulted in an increased incidence of lymphoreticular tumors, primarily in females. There are questions about the diagnostic criteria used in this study. The NOAEL for this tumor was <250 mg/kg/day. [(b) (4)] was not genotoxic in a battery of mutagenicity studies, indicating that, if it is a carcinogen, it does not induce tumors through a genotoxic mechanism. [(b) (4)] has also been considered to be a non-genotoxic carcinogen and EPA has been reluctant to classify its human oncogenic potential. However, EPA has done linear extrapolation of risk on [(b) (4)] tumor incidences using the female lymphoreticular tumors, and liver (mouse) and kidney (rat) tumors found in inhalation studies.

In a developmental toxicity study, administration of [(b) (4)] to pregnant rats from gestation days 6-15 resulted in decreased maternal body weight gain and food consumption ([(b) (4)] ppm). Developmental toxicity was observed as an increased numbers of fetuses with [(b) (4)] but only at maternally toxic dose levels. It did not cause neuropathology in a 13-week neurotoxicity study, but did result in decreased activity in a figure-eight maze and unperturbed activity in the FOB (females only) at a dose level of [(b) (4)] ppm (inhalation).

Thus, Lek Pharmaceuticals uses these NOAELs from inadequate studies to determine the safety margins in humans (see below) and state that the amounts of [(b) (4)] that can pose concerns are 30,000 times less in their atorvastatin tablets vs the amounts that can produce the bad effects of [(b) (4)] in humans, suggesting that there is 30,000 times safety margin in rats to humans in [(b) (4)] levels.

Assessment of Risk

Several approaches have been taken to the assessment of potential risk from exposure to [(b) (4)] at levels up to [(b) (4)] Atorvastatin tablets. Each of these approaches indicates that the presence of these levels of [(b) (4)] would be acceptable.

Margin of Exposure Calculations

One approach to estimating potential risk of residual [(b) (4)] in Atorvastatin tablets is to compare the maximum exposure level to No Observed Adverse Effect Levels (NOAELs) or Lowest Observed Adverse Effect Levels (LOAELs) in clinical and non-clinical studies.

No clinical studies are available for [(b) (4)] In non-clinical studies, [(b) (4)] has been tested by both oral and inhalation routes. As discussed above, the metabolic disposition of [(b) (4)] is expected to be quite similar for both inhalation and oral routes, but for completeness sake, results from both routes are shown in the following calculations.

The lowest oral LOAEL (based on an increase in questionably diagnosed lymphoreticular tumors in female rats) was from a lifetime carcinogenicity study and was <250 mg/kg/day. The highest dose level of [(b) (4)] that will result from administration of the atorvastatin tablets is [(b) (4)] mg/day. Assuming a 60 kg body, the maximum human exposure on a per kg body weight per day basis is calculated to be [(b) (4)] kg or [(b) (4)] mg/kg/day. The margin of exposure is calculated by dividing the LOAEL in experimental animals by the estimated maximum dose level in humans as follows:

Margin of Exposure = [(b) (4)]

Thus, the lowest dose of [(b) (4)] that potentially caused adverse effects in experimental animals is about 30,000 times more than the estimated maximum human dose of [(b) (4)] from taking Atorvastatin.

This does not establish a safe level of [(b) (4)]

According to the sponsor, the highest dose of [(b) (4)] that will result in a subject taking MRHD of atorvastatin will be [(b) (4)] mg/day (or [(b) (4)] mg/kg/day or [(b) (4)] mg/m^2/day, based on a 60 kg weight of an average person). Assuming the NOAEL dose of [(b) (4)] in rats from an oral carcinogenicity study is <250 mg/kg/day (or <1500 mg/m^2/day), this dose will provide the exposures of [(b) (4)]

fold in rats to humans, but note that the above dose is not a NOAEL but actually produces tumors in rats.

As stated in a previous consult review on (b) (4) (3/13/06), this (b) (4) is used in (b) (4) It can form (b) (4) when it (b) (4). NIOSH recommends (b) (4) ppm (b) (4) only over a 10-hour inhalation period. The proposed level of (b) (4) ppm (b) (4)) for oral administration is 10-fold higher than the NIOSH recommended inhalation levels.

Note that Lek Pharmaceutical's atorvastatin drug product will have this (b) (4) present in the tablets at levels of (b) (4) ((b) (4) mg/day) every day, and this drug will be used by patients for a long time. NIOSH states that (b) (4) ppm (less than 2 fold higher dose) for 5 minutes was irritating to eyes and mucus membrane. Toxicity with (b) (4) not only include anesthesia, somnolence and respiratory depression, but (b) (4) ppm increase liver and kidney weights in rats, hepatocellular hypertrophy in the liver and produce hyaline droplet formation in convoluted tubules in the kidney. We do not know what kind of toxicity it will produce when given orally, as most supporting studies provided by Lek Pharmaceuticals including human exposures are based on inhalation route of administration.

Internal Recommendations: No adequate toxicity studies have been documented with (b) (4) by oral route of administration to qualify levels of (b) (4) present in atorvastatin drug product. Therefore, it is hard to specify the maximum allowable amounts of (b) (4) Sponsor (Lek Pharmaceuticals) needs to qualify the proposed residual levels of (b) (4) by oral route (the intended route of administration in humans). A 1-month full quality assured/GLP toxicity study in one species with the proposed drug product and the reference listed drug with toxico-kinetics, will likely provide the necessary information as well as provide qualification of any differences in (b) (4) /impurity/degradant profiles between the products. The toxicity studies should clearly identify target organs of toxicity and NOAELs. Inclusion of a recovery group is suggested to evaluate the reversibility of toxicity findings.

Signatures (optional):

Reviewer Signature _____

Supervisor Signature_____
Concurrence Yes ___ No ___

cc: IND Arch
HFD-510
HFD-510/davisbruno/antonipillai/galliers/aljuburi/Trang Tran/Gil Jong Kang /Ripper, L
File name: ANDA 77-575-OGD consult (Lek atorvastatin calcium)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	SANDOZ INC	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

INDRA ANTONIPILLAI
08/26/2010
Please see the internal pharmacology/toxicology recommendations.

KAREN L DAVIS BRUNO
08/26/2010

DOCUMENT INFORMATION PAGE

This page is for FDA internal use only.
Do NOT send this page with the letter.

Application #(s):	Global
Drafted by:	Nw\6\2\10\
Project Manager Endorsement:	HFD-617/D.Doan/
Tim Ames Endorsement:	
File Location:	Eroom-077424tra.own.multi
Notes:	

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDAs (See Attachment)

Sandoz Inc.
Attention: William Kwok
Associate Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540

Dear Sir:

We acknowledge receipt of your communications dated October 23, 2009, submitted as required by the provisions of Regulation 21 CFR 314.72(a) and Section 505(k) of the Federal Food, Drug and Cosmetic Act for the abbreviated new drug application (ANDA) for the drug products listed in the attachment.

Your letter details the transfer of ownership of the ANDAs from Lek Pharmaceuticals d.d. to Sandoz Inc.

Pursuant to 21 CFR 314.72(b), the new owner shall advise FDA about any change in the conditions of the pending applications.

The material submitted is being retained as part of your applications.

Sincerely yours,

{See appended electronic signature page}

William P. Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Abbreviated applications being transferred from Lek Pharmaceuticals d.d. to Sandoz Inc.

ANDAs:	**Pending Drug Products**
077424	Losartan Potassium Tablets, 25 mg, 50 mg and 100 mg
077438	Levofloxacin Tablets, 250 mg, 500 mg and 750 mg
077575	Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg
077948	Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg, 100 mg/25 mg and 100 mg/12.5 mg
(b) (4)	
078739	Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg and 10 mg
079230	Rizatriptan Benzoate Tablets, 5 mg and 10 mg (base)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	GI-1	LEK PHARMACEUTICALS D D	ATORVASTATIN CALCIUM
			(b) (4)
ANDA-77948	GI-1	LEK PHARMACEUTICAL AND CHEMICAL CO DD	LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE
ANDA-77424	GI-1	LEK PHARMACEUTICALS D D	LOSARTAN POTASSIUM
ANDA-77438	GI-1	LEK PHARMACEUTICALS D D	LEVOFLOXACIN
ANDA-79230	GI-1	SANDOZ INC	RIZATRIPTAN BENZOATE
ANDA-78739	GI-1	LEK PHARMACEUTICALS DD	RIZATRIPTAN BENZOATE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TIMOTHY W AMES
08/16/2010
Signing for Wm. Peter Rickman

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION			**REQUEST FOR CONSULTATION** **Consult No: 2010-0442**	
TO *(Division/Office)* DMEP - HFD-510 Thru: Leah Ripper, ODEII - HFD 102			**FROM:** Gil jong Kang	
DATE: 8/10/2010	**IND NO.**	**ANDA NO.** 77575	**TYPE OF DOCUMENT** Amendment	**DATE OF DOCUMENT** 3/13/2006,
NAME OF DRUG Atorvastatin Calcium Tablets		**PRIORITY CONSIDERATION** 15 days	**CLASSIFICATION OF DRUG** antihyperlipidemic	**DESIRED COMPLETION DATE** 8/25/2010

NAME OF FIRM Sandoz Inc.

REASON FOR REQUEST

I. GENERAL

Γ NEW PROTOCOL
Γ PROGRESS REPORT
Γ NEW CORRESPONDENCE
Γ DRUG ADVERTISING
Γ ADVERSE REACTION REPORT
Γ MANUFACTURING CHANGE/ADDITION
Γ MEETING PLANNED BY _____
Γ PRE NDA MEETING
Γ END OF PHASE II MEETING
Γ RESUBMISSION
Γ SAFETY/EFFICACY
Γ PAPER NDA
Γ CONTROL SUPPLEMENT
Γ RESPONSE TO DEFICPENCY LETTER
Γ FINAL PRINTED LABELING
Γ LABELING REVISION
Γ ORIGINAL NEW CORRESPONDENCE
Γ FORMULATIVE REVIEW
X *OTHER ('specify below)*

II.BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
Γ TYPE A OR B NDA REVIEW Γ END QF PHASE II MEETING Γ CONTROLLED STUDI ES Γ PROTOCOL REVIEW Γ OTHER	Γ CHEMISTRY Γ PHARMACOLOGY Γ BIOPHARMACEUTICS Γ OTHER

III.BIOPHARMACEUTICS

□ DISSOLUTION
□ PROTOCOL-- BIOPHARMACEUTICS
□ IN--VIVO WAIVER REQUEST
□ DEFICIENCY LETTER RESPONSE
□ BIOAVAILABILITY STUDIES
□ PHASE IV STUDIES

IV.DRUG EXPERIENCE

□ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
□ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
□ CASE REPORTS OF SPECIFIC *REACTIONS(List below)*
□ COMPARATIVE RISK ASSESSEMENT ON GENERIC DRUG GROUP
□ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
□ SUMMARY OF ADVERSE EXPERIENCE
POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

□ CLINICAL □ PRECLINICAL

COMMENTS
Please request a Pharm/Tox consult on Lek's report of "Qualification of (b) (4) in Atorvastatin Calcium" for ANDA 077575.In the amendment, Lek has tightened the limit for (b) (4) ppm from (b) (4) ppm based on their toxicological report.Previously a Pharm/Tox consult was r (b) (4) for DMF180 k's Atorvastatin Calcium. Please note Lek manufactures both the drug substance and du wever, the consult result on 13-MAR-2006 (attached file) did not specify the allowable amount of (b) (4) Please ask Pharm/Tox reviewer to establish the maximum allowable amount of (b) (4) for A um Tablets as this is a long term use drug.

Please cc Trang Tran, HFD-617 (Trang.Tran@fda.hhs.gov) on the review when it is being checked into DFS. Thank you.

SIGNATURE OF REQUESTER	METHOD OF DE LIVERY *(Check one)* □ MAIL □ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

FORM FDA 3291 (7/83)

cc: ANDA
Drug File Folder

Pharmacology/Toxicology Consult Request
March 13, 2006

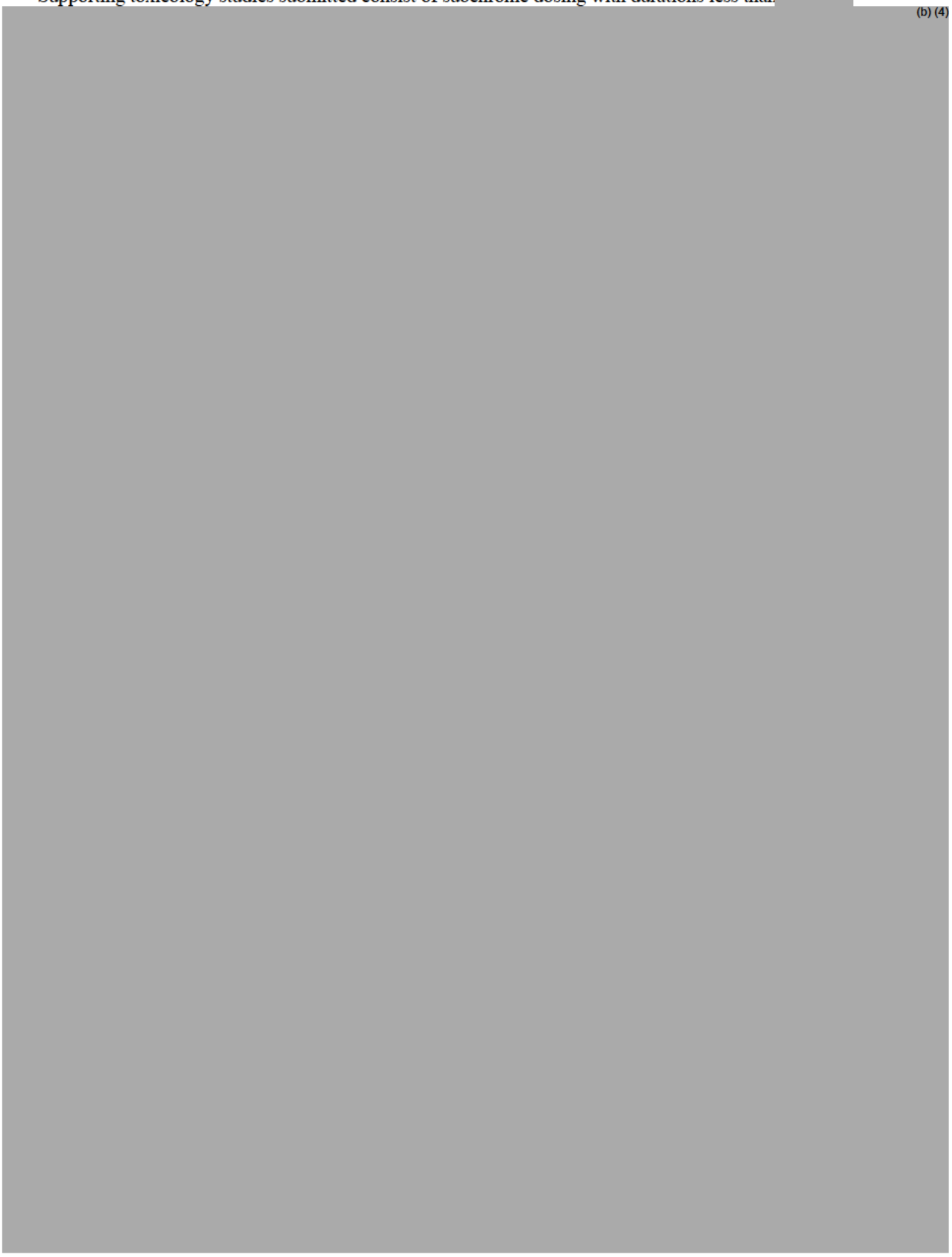
To: Peter Chen HFD-617
From: Karen Davis-Bruno PhD; DMEP
Re: DMF 018082 Lek Pharmaceuticals DD

A consult received 3/10/06, requests review of a proposed residual [redacted] ([redacted] limit of [redacted] ppm [redacted]) for atorvastatin, calcium. The maximum concentration of [redacted] for a MRHD of 80 mg/day atorvastatin is [redacted] mg/m^2). Lek Pharmaceuticals has provided summary information of TOXNET searches based on CAS # 108-20-3.

[redacted]

Supporting toxicology studies submitted consist of subchronic dosing with durations less than (b) (4)

(b) (4)



Reproductive toxicology studies revealed an increased incidence of [redacted] in fetuses from the mid and high dose groups, however it is noted in the presence of maternal toxicity (decreased weight gain, food). Sperm parameters from the left cauda epididymis of 10 males from control and [redacted] ppm [redacted] were evaluated for morphology and count to verify the findings in the subchronic toxicology studies, the results from this study were unremarkable.

Human experience: [redacted] is used in [redacted]. It can form [redacted]. NIOSH recommends [redacted] over a 10 h inhalational period as an exposure limit. The proposed level of [redacted] oral is 20-fold higher than the NIOSH recommended inhalational level. Levels up to [redacted] ppm for 5 minutes were irritating to mucosal membranes. Intoxication of [redacted] includes [redacted]. Inhalational occupational exposure suggests that [redacted] daily for 20 days had no adverse effect.

Conclusions: It is unclear what the safe level of [redacted] is by oral route since all the supporting studies provided, including the NIOSH human exposure level is based on inhalational exposure. Toxicokinetic studies have not been provided to compare exposures via these different routes. Metabolic profiles are not provided, although the sponsor notes that [redacted] forms [redacted] and is readily absorbed into plasma from the lung. The fate or toxicity of these reactive [redacted] moieties is not addressed. In addition there are no adequate chronic studies with either an oral or inhalational route of exposure in animals. The proposed levels of [redacted] exposure ([redacted] mg/m^2) assuming complete absorption in the human GI tract are significantly higher ($\geq$ 20-fold) than those levels with observed toxicity findings in animals and the NIOSH exposure level by inhalation ([redacted]) however information regarding the safe level of oral [redacted] exposure has not been established.

Qualification of (b) (4) in Atorvastatin

Introduction

(b) (4)

16 pages have been withheld as b4 (CCI/TS) immediately following this page

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	LEK PHARMACEUTICALS D D	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SARAH K NGUYEN
08/10/2010

TRANG Q TRAN
08/10/2010

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

SANDOZ

June 15, 2010

Office of Generic Drugs, HFD-600
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

– PATENT AMENDMENT –

Re: Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, and 80 mg
ANDA 077575

Dear Sir/Madam:

Sandoz Inc. is hereby submitting a "Patent Amendment" to our pending application, Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg, and 80 mg, ANDA 077575. The purpose of this correspondence is to provide revised Patent Certification to the application.

This submission is in electronic format (CD). Enclosed CD contains:

- 356h
- Cover Letter
- Revised Patent Certification
- Orange Book Patent Information

CHANGE IN OFFICIAL CONTACT INFORMATION

The new Regulatory Affairs contact person's name and contact information is provided below. This information will help facilitate future communication between the agency and Sandoz:

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

William Kwok
Ph: (609) 627-8854
Fax: (609) 395- 2792
Email: william.kwok@sandoz.com

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

A letter of non-repudiation agreement was submitted by Sandoz Inc. on November 30, 2007. However, we are providing hard copies of our Cover Letter and FDA Form 356h with original signature.

For any communication regarding this ANDA application, please contact me, at (609)-627-8854 (phone) or (609)-395-2792 (facsimile) or william.kwok@sandoz.com (email).

Sincerely,

Robert A. Quatten for William Kwok

William Kwok
Director, Regulatory Affairs

SANDOZ

William Kwok
Director, Regulatory Affairs

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8854 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

PATENT AND EXCLUSIVITY CERTIFICATION

Name of Applicant:	Sandoz Inc.
Address of Applicant:	506 Carnegie Center, Suite 400, Princeton, NJ 08540
Drug Product:	Atorvastatin Calcium Tablets, EQ 10 mg, 20 mg, 40 mg & 80 mg Base
RLD:	LIPITOR (atorvastatin calcium) EQ 80 mg Base tablets

(1) AMENDED PATENT CERTIFICATION STATEMENT

Sandoz Inc. ("Sandoz"), by this ANDA, is requesting approval for atorvastatin calcium tablets, EQ 10 mg, 20 mg, 40 mg & 80mg Base (the "Sandoz Product"). Upon information and belief, Sandoz believes that Pfizer is the holder of the New Drug Application No. 020702 for the above-identified Reference Listed Drug ("RLD").

Sandoz hereby certifies that, upon information and belief, the following United States Patents is/are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* for the above-identified RLD:

Patent No.	Expires	Patent Owner	PEDS
4681893	Sep 24, 2009	Warner-Lambert	Mar 24 2010
5273995	Dec 28,2010	Warner-Lambert	Jun 28, 2011
5686104	Nov 11, 2014	Warner-Lambert	May 11, 2015
5969156	Jul 8, 2016	Warner-Lambert	Jan 8, 2017
6126971	Jan 19, 2013	Warner-Lambert	Jul 19, 2013
RE40667	Dec 28, 2010	Warner-Lambert	Jun 28, 2011

Sandoz submits the following certifications to these patents:

Paragraph III Certification for U.S. Pat. Nos. 4681893, 5273995 and RE40667

Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), Sandoz hereby certifies that the approval of the Sandoz Product is sought to be effective upon expiration of the following U.S. Patents 4681893, 5273995 and RE40667.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Paragraph IV Certification For U.S. Pat. Nos. 5686104, 5969156 and 6126971

Pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), Sandoz hereby certifies that the claims of the following U.S. Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Product: 5686104, 5969156 and 6126971.

Sandoz have complied with the requirements of 21 C.F.R. § 314.95 with respect to providing notice to each patent owner and to the holder of the approved application for the above-identified RLD.

(2) EXCLUSIVITY STATEMENT

Sandoz hereby certifies that the expired exclusivity below is the only associated with the above-identified RLD.

Exclusivity	Expired	Description
I-523	Mar 2, 2010	USE IN ADULT PATIENTS WITH CLINICALLY EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF NONFATAL MYOCARDIAL INFARCTION, FATAL AND NONFATAL STROKE, ANGINA, REVASCULARIZATION PROCEDURES AND HOSPITALIZATION FOR CONGESTIVE HEART FAILURE

Robert A. Quattlebaum for William Kwok

William Kwok
Director, Regulatory Affairs
Sandoz Inc.

15-June-2010
Date

Linda O'Dea
Sr. Director Regulatory Affairs

Sandoz Inc.
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone: +1 862-778-5234
Fax: +1 973-781-3710
Email : linda.odea@sandoz.com

May 17, 2010

Office of Generic Drugs
Center for Drug Evaluation & Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

- GENERAL CORRESPONDENCE –
CHANGE IN OFFICIAL CONTACT INFORMATION

Re: ANDA Nos. 090999, 200154, 200159, 078364, (b) (4) , 078670, 091273, (b) (4) , 078555, 078739, 079230, 201047, (b) (4) , (b) (4) , 201048, 090107, 077575, 078702, 078901, (b) (4) , 200158, (b) (4)

Dear Sir or Madam:

This correspondence is being submitted to advise you that Sandoz Inc., the holder and owner of the above-listed ANDAs, has changed the contact person.

With immediate effect, Sandoz primary contact for the following ANDAs is Mr. William Kwok, Associate Director of Regulatory Affairs, Sandoz Inc.

ANDA #	Product name
090999	Aprepitant Capsules, 40 mg, 80 mg and 125 mg
200154	Cisatracurium Besylate Injection (Preservative Free)
200159	Cisatracurium Besylate Injection
078364	Desloratadine Tablets, 5 mg
(b) (4)	(b) (4)
(b) (4)	(b) (4)

Table continues on the next page

SANDOZ

Sandoz Inc.
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone: +1 862-778-5234
Fax: +1 973-781-3710
Email : linda.odea@sandoz.com

Table continues from the previous page	
078670	Pioglitazone Hydrochloride Tablets, 15 mg, 30 mg, and 45 mg
091273	Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15/ 500 mg and 15/ 850 mg
(b) (4)	
078555	Repaglinide Tablets, 0.5 mg, 1 mg and 2 mg
078739	Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg and 10 mg
079230	Rizatriptan Benzoate Tablets, 5 mg and 10 mg
201047	Ropinirole Hydrochloride Extended-Release Tablets, 2 mg, 3 mg, 4 mg, 6 mg, and 8 mg
(b) (4)	
(b) (4)	
(b) (4)	
201048	Sterile Vancomycin Hydrochloride for Injection USP, 5 g, 10 g
090107	Zolpidem Tartrate Extended-Release Tablets, 6.25 mg and 12.5 mg
077575	Atrovastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg
078702	Candesartan Cilextil Tablets, 4 mg, 8 mg, 16 mg and 32 mg
078901	Olanzapine/Fluoxetine Capsules, 6/25 mg, 12/25 mg, 12/50 mg, 6/50 mg
(b) (4)	
(b) (4)	
(b) (4)	
200158	Diclofenac Sodium DR/Misoprostol Tablets, 50/0.2 mg, 75/0.2 mg
(b) (4)	

The new Regulatory Affairs contact person's name and contact information is provided below. This information will help facilitate future communication between the agency and Sandoz:

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

William Kwok.
Ph: (609) 627-8854
Fax: (609) 395- 2792

If you require additional information regarding this change, feel free to call. I can be reached at (862) 778-5234.

Sincerely,

Linda O'Dea
Senior Director, Regulatory Affairs, Sandoz Inc.

lek

a Sandoz company

Lek Pharmaceuticals d.d.
Verovškova 57
SI - 1526 Ljubljana
Slovenia
Phone: +386 1 580 21 11
Fax: +386 1 568 35 17
www.lek.si

May 17, 2010

Ms. Nadine Warren
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room/Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

-GENERAL CORRESPONDENCE –
TRANSFER OF ANDA OWNERSHIP

Re: ANDA #s 77-575, 78-739, 79-230, 77-438, 77-424, 77-948, 78-015, (b) (4)

Dear Ms. Warren,

Reference is also made to the phone conversation that you had with Mr. William Kwok of Sandoz Inc., on May 5, 2010, with reference to the submission dated October 23, 2009. You requested that Sandoz submit to your attention, a change of ownership letter with the Lek letterhead.

As per the telephone conversation, we are submitting this correspondence. Lek Pharmaceuticals d.d. is hereby advising the FDA that Sandoz Inc. is the holder and owner of the following ANDAs.

Product Name	ANDA #
Atrovastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, 80 mg	77-575
Rizatriptan Benzoate ODT, 5 mg and 10 mg	78-739
Rizatriptan Benzoate Tablets, 5 mg and 10 mg	79-230
Levofloxacin Tablets, 250 mg, 500 mg and 750 mg	77-438
Losartan Potassium Tablets, 25 mg, 50 mg, 100 mg	77-424
Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg,100 mg/25 mg and 100 mg/12.5 mg	77-948
Tamsulosin Hydrochloride Capsules, 0.4 mg	78-015
(b) (4)	

lek

a Sandoz company

On January 1, 2008, Lek Pharmaceuticals d.d and Sandoz Inc., were integrated. Sandoz Inc., will be distributing the above products in the U.S.A after the final approval of the ANDAs by the FDA. As such, Sandoz Inc., will be the holder of the above mentioned ANDAs.

This submission is a Formal Transfer of Ownership. The primary contact for above ANDA#s 77-575, 78-739, 79-230, 77-438, 77-424, 78-015, and (b) (4) is:

Mr. William Kwok
Associate Director, Regulatory Affairs
Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540

If you have any questions or require any additional information regarding the transfer of ownership of the above ANDA#s 77-575, 78-739, 79-230, 77-438, 77-424, 77-948, 78-015, and (b) (4) please contact Mr. William Kwok by telephone at (609) 627-8854, by facsimile at (609) 395-2792.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and return it in the self-addressed stamped envelope.

Sincerely,

Ksenija Butenko Černe
Member of the Board of Management

Vojmir Urlep
President of the Board of Management

SANDOZ

Vamsi K. Nama
Regulatory Associate II

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-5215 (Direct)
Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

March 01, 2010

Teresa Vu
Division of Bioequivalence-I
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

– BIOEQUIVALENCE AMENDMENT –

RE: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg
ANDA 077575

Dear Ms. Vu,

Sandoz Inc. is hereby submitting a bioequivalence amendment to our pending Abbreviated New Drug Application (ANDA 077575), Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, as required by Section 505(j) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR 314.96.

The following is provided in response to the Agency's deficiency letter dated, December 11, 2009. A copy of the deficiency letter (**FDA letter.pdf**) is also provided for ease of review.

The Division of Bioequivalence (DBE) has completed its review of the submission acknowledged on the cover page and the following deficiencies have been identified:

FDA COMMENTS:

1. ***For your fasting study (Study No. 80018), you did not submit complete raw numerical data of all study sample assay and reassay runs. The raw data should include the peak area/height for the drug, peak area/height for the internal standard, the ratio of the peak area/height for the drug to the peak area/height for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each assayed and reassayed sample, calibration standard samples, and quality control samples.***

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

Sandoz Response:
Sandoz acknowledges the agency's comment, the complete raw data of all study sample assay and reassay runs for Study No. 80018 and the summary of sample reassay coding are enclosed on the CD (**Attachment-1**).

2. ***Your dissolution testing data based on the FDA-recommended dissolution method are adequate only for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. However, for the 40 mg (Lot # A01198003I) strength of the test product, it was observed that one tablet had unusually low dissolution at 5, 10 and 15 min which contributed to very high coefficient of variation (CV%) for the mean dissolution values at these sampling time points. To confirm the reproducibility and accuracy of your dissolution data from the 40 mg strength of the test product, please repeat the dissolution testing using the following FDA-recommended method for the 40 mg strength only. The DBE will set the specification for all strengths of the test product after evaluating the additional dissolution data.***

   The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate Buffer, pH 6.8, at 37 ± 0.5 ^{0}C, using USP apparatus II at 75 rpm.

   Sandoz Response:
   We acknowledge the agency's comment to confirm the reproducibility and accuracy of dissolution data for 40 mg strength, Sandoz is submitting the repeated dissolution testing data using the FDA recommended method. The dissolution testing data is enclosed on the CD (**Attachment-2**).

This correspondence is being submitted electronically on 1 CD. The size of submission is approximately 8 MB. This submission is virus free. The files were checked for virus using McAfee Virus Scan Enterprise Version 8.5*i*. Enclosed CD contains:

- 356h
- Cover letter
- FDA letter
- Attachment-1
- Attachment-2

A letter of non-repudiation agreement was submitted by Sandoz Inc. on November 30, 2007. However, we are providing hard copies of our cover letter and FDA Form 356h with original signature.

SANDOZ

Sandoz Inc.
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609-627-8500 (Gen)
Fax: 609-395-2792

For any communication regarding this ANDA application, please contact:

William Kwok
Phone: (609) 627-8854
Fax : (609) 395-2792
Email: william.kwok@sandoz.com.

Sincerely,

N. Vamsi Krishna.

Vamsi K. Nama
Associate-II, Regulatory Affairs

BIOEQUIVALENCE AMENDMENT

ANDA 077575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (240-276-9327)

APPLICANT: Lek Pharmaceuticals d.d.

TEL: (609) 627-8885

ATTN: Srinivasa Rao

FAX: 609-395-2792

FROM: Teresa Vu

FDA CONTACT PHONE: (240) 276-8782

Dear Sir:

This facsimile is in reference to the bioequivalence data submitted on February 11, 2005, pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to your amendment dated March 11, 2009.

The Division of Bioequivalence has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached **1** page. This facsimile is to be regarded as an official FDA communication and unless requested, a hard-copy will not be mailed.

You should submit a response to these deficiencies in accord with 21 CFR 314.96. Your amendment should respond to all the deficiencies listed. **Facsimiles or partial replies will not be considered for review.** Your cover letter should clearly indicate:

Bioequivalence Response to Information Request

If applicable, please clearly identify any new studies (i.e., fasting, fed, multiple dose, dissolution data, waiver or dissolution waiver) that might be included for each strength. We also request that you include a copy of this **communication with your response.**
Please submit a copy of your amendment in an archival (blue) jacket and unless submitted electronically through the gateway, a review (orange) jacket. Please direct any questions concerning this communication to the project manager identified above.

Please remember that when changes are requested to your proposed dissolution methods and/or specifications by the Division of Bioequivalence, an amendment to the Division of Chemistry should also be submitted to revise the release and stability specification. We also recommend that supportive dissolution data or scientific justification be provided in the CMC submission to demonstrate that the revised dissolution specification will be met over the shelf life of the drug product.

SPECIAL INSTRUCTIONS:

Please submit your response in electronic format. This will improve document availability to review staff.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address

ANDA: 077575

APPLICANT: Lek Pharmaceuticals d.d

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. For your fasting study (Study No. 80018), you did not submit complete raw numerical data of all study sample assay and reassay runs. The raw data should include the peak area/height for the drug, peak area/height for the internal standard, the ratio of the peak area/height for the drug to the peak area/height for the internal standard, dilution factor (if any), and the corresponding calculated concentration for each assayed and reassayed sample, calibration standard samples, and quality control samples.

2. Your dissolution testing data based on the FDA-recommended dissolution method are adequate only for the 10 mg (Lot # A01179803I), 20 mg (Lot # A01196903I) and 80 mg (Lot # 30004016) strengths. However, for the 40 mg (Lot # A01198003I) strength of the test product, it was observed that one tablet had unusually low dissolution at 5, 10 and 15 min which contributed to very high coefficient of variation (CV%) for the mean dissolution values at these sampling time points. To confirm the reproducibility and accuracy of your dissolution data from the 40 mg strength of the test product, please repeat the dissolution testing using the following FDA-recommended method for the 40 mg strength only. The DBE will set the specification for all strengths of the test product after evaluating the additional dissolution data.

   The dissolution testing should be conducted in 900 mL of 0.05 M Phosphate Buffer, pH 6.8, at 37 ± 0.5 ^{0}C, using USP apparatus II at 75 rpm.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence I
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77575	ORIG-1	LEK PHARMACEUTICALS D D	ATORVASTATIN CALCIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DALE P CONNER
12/11/2009

SANDOZ

Joseph A. Carrado, M.Sc., R.Ph.
Vice President,
Regulatory Affairs

Sandoz
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: 609 627- 8500
Fax: 609 627- 8684
www.us.sandoz.com

October 23, 2009

Mr. Gary J. Buehler, RPh
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room/Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

-GENERAL CORRESPONDENCE –
CHANGE IN ANDA OWNERSHIP

Re: ANDA #s 77-575, 78-739, 79-230, 77-438, 77-424, 77-948, 78-015, (b) (4)

Dear Mr. Buehler,

This correspondence is being submitted to advise you that on January 1, 2008, the business activity of Lek Pharmaceuticals, Inc. ("Lek") was transferred to its related affiliate, Sandoz Inc. ("Sandoz"), rendering Lek an inactive legal entity. Prior to this transfer, Lek had applied for the above referenced ANDAs for products to be distributed in the future. However, due to the transfer of its business activities to Sandoz, Sandoz will now be distributing the above products in the United States, after final approval of the ANDAs by the FDA. As such, Sandoz, will be the holder of the above mentioned ANDAs.

Pursuant to the foregoing, Sandoz is now the holder and owner of the following ANDAs:

Product Name	ANDA #
Atrovastatin Calcium Tablets, 10 mg, 20mg, 40 mg, 80 mg	77-575
Rizatriptan Benzoate ODT, 5 mg and 10 mg	78-739
Rizatriptan Benzoate Tablets, 5 mg and 10 mg	79-230
Levofloxacin Tablets, 250 mg, 500 mg and 750 mg	77-438
Losartan Potassium Tablets, 25 mg, 50 mg, 100 mg	77-424
Losartan Potassium and Hydrochlorothiazide Tablets, 50 mg/12.5 mg,100 mg/25 mg and 100 mg/12.5 mg	77-948
Tamsulosin Hydrochloride Capsules, 0.4 mg	78-015
(b) (4)	

This correspondence is a Formal Transfer of Ownership. The primary Sandoz contact for the above referenced ANDAs is:

Srinivasa S. Rao, Pharm.D.
Director Regulatory Affairs,
Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Telephone: (609) 627-8885
Facsimile: (609) 395-2792

If you have any questions or require any additional information regarding the transfer of ownership of the above ANDAs, please do not hesitate to contact Mr. Rao.

Please acknowledge your receipt of this notification by signing and dating the enclosed copy of the cover letter and return it in the enclosed self-addressed stamped envelope.

Sincerely,

Joseph A. Carrado, M.Sc., R.Ph.
Vice President, Regulatory Affairs

AGREED AND ACCEPTED as of the
23rd day of October, 2009

Center for Drug Evaluation and Research
Food and Drug Administration

By: _____
Name:

Encl.

October DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
SANDOZ INC.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
(609) 627-8885 (Dir.)/(609) 627-8500 (General)	(609) 395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
506 Carnegie Center Suite 400 Princeton, NJ 08540	NOT APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-575

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Atorvastatin Calcium Tablets	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
[R-(R*,R*)]-2-(4-fluorophenyl)-ß,δ-dihoydroxy-5-(1-methylethyl)-3-phenyl-4[(phenylamino)carbonyl]-H-pyrrole-1-heptanoic acid, calcium salt (2:1)	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
TABLETS	10 mg, 20 mg, 40 mg, and 80 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
Cholesterol Lowering

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug LIPITOR (atorvastatin calcium) Tablets Holder of Approved Application PFIZER

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA Ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Please refer to the Original Submission

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

Please refer to the Original Submission

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA ownership

CERTIFICATION

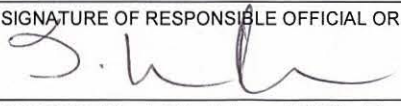
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D., Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400, Princeton, NJ 08540	(609) 627-8885 (Direct) (609) 627-8500 (General)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
SANDOZ INC.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
(609) 627-8885 (Dir.)/(609) 627-8500 (General)	(609) 395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* **IF APPLICABLE**
506 Carnegie Center Suite 400 Princeton, NJ 08540	NOT APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-575

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Rizatriptan Benzoate Orally Disintegrating Tablets	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine monobenzoate	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
ORALLY DISINTEGRATING TABLETS	5 mg and 10 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
For the treatment of schizophrenia

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug MAXALT-MLT Holder of Approved Application MERCK

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA Ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Please refer to the Original Submission

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

Please refer to the Original Submission

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA Ownership

CERTIFICATION

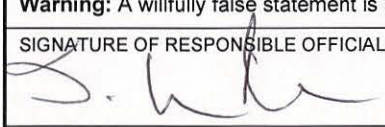
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D., Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400, Princeton, NJ 08540	(609) 627-8885 (Direct) (609) 627-8500 (General)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
SANDOZ INC.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	FACSIMILE *(FAX)* Number *(Include Area Code)*
(609) 627-8885 (Dir.)/(609) 627-8500 (General)	(609) 395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 506 Carnegie Center, Suite 400, Princeton, NJ 08540	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE: NOT APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 78-739

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Rizatriptan Benzoate Orally Disintegrating Tablets	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine monobenzoate	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
ORALLY DISINTEGRATING TABLETS	5 mg and 10 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
For the treatment of schizophrenia

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug MAXALT-MLT Holder of Approved Application MERCK

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA Ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED N/A THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Please refer to the Original Submission

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

Please refer to the Original Submission

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA Ownership

CERTIFICATION

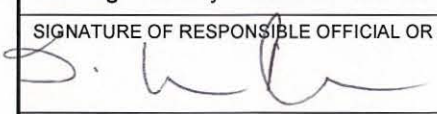
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D., Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400, Princeton, NJ 08540	(609) 627-8885 (Direct) (609) 627-8500 (General)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: August 31, 2005
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Sandoz Inc.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
609-627-8885 (Direct)/(609) 627-8500 (General)	609-395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
506 Carnegie Center Suite 400 Princeton, NJ 08540	

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-438

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
LEVOFLOXACIN TABLETS, 250 mg, 500 mg and 750 mg	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* (-)-(s)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-Piperazinyl)-7-oxo-7h-pyrido(1,2,3,-de)-1,4-benzoxazine-6-carboxylic acid

CODE NAME *(If any)*: N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Film-coated tablets	250 mg, 500 mg and 750 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
For the treatment of variety infections caused by bacteria susceptible to levofloxacin.

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: LEVAQUIN (levofloxacin) Tablets — Holder of Approved Application: ORTHO-McNEIL PHARMACEUTICALS, Inc.

TYPE OF SUBMISSION *(check one)*
☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: N/A — THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA ownership

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
S. Rao	Srinivasa S. Rao, Pharm.D. Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Princeton, NJ 08540	(609)627-8885(D)/(609)627-8500(Gen)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CDER, HFD-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Sandoz Inc.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
(609) 627-8885 (Dir) / 609-627-8500 (Gen)	609-395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 506 Carnegie Center Princeton, NJ 08540	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-424

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
LOSARTAN POTASSIUM TABLETS	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* 2-butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol monopotassium salt

CODE NAME *(If any)*: N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
TABLETS	25 mg, 50 mg, 100 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
Hypertension, hypertensive patients with left ventricular hypertrophy

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug: COZAAR TABLETS Holder of Approved Application: MERCK & CO

TYPE OF SUBMISSION *(check one)*
☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA Ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: N/A THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA Ownership

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
S. Rao	Srinivasa S. Rao, Pharm.D. Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Princeton, NJ 08540	(609)627-8885(D)/(609)627-8500(Gen)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Sandoz Inc.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	FACSIMILE *(FAX)* Number *(Include Area Code)*
(609) 627-8885 (Direct) / (609) 627-8500 (Gen)	609-395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 506 Carnegie Center Princeton, NJ 08540	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-948

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE TABLETS	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
Please refer to Continuation Sheet	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
TABLETS	50mg/12.5mg, 100mg/12.5mg, 100mg/25mg	ORAL

(PROPOSED) INDICATION(S) FOR USE: (1) TREATMENT OF HYPERTENSION
(2) TO REDUCE RISK OF STROKE IN PATIENTS WITH HYPERTENSION AND LEFT VENTRICULAR HYPERTROPHY

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)* ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug HYZAAR TABLETS Holder of Approved Application MERCK

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
TELEPHONE AMENDMENT

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED N/A THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA Ownership

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
S. Rao	Srinivasa S. Rao, Pharm.D. Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Princeton, NJ 08540	(609)627-8885(D)/(609)627-8500(Gen)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Sandoz Inc.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
609-627-8885 (Direct)/(609) 627-8500 (General)	(609) 395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
506 Carnegie Center, Suite 400 Princeton, NJ 08540	

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 78-015

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY	
Tamsulosin Hydrochloride Capsules, 0.4 mg	N/A	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*		**CODE NAME** *(If any)*
Tamsulosin hydrochloride: (-)-(R)-5-[2-[[2-(0-ethoxyphenoxy)ethyl]amino]propyl]-2-methoxy benzenesulfonamide monohydrochloride		N/A
DOSAGE FORM:	**STRENGTHS:**	**ROUTE OF ADMINISTRATION:**
Capsules	0.4 mg	ORAL

(PROPOSED) INDICATION(S) FOR USE:
Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

APPLICATION DESCRIPTION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Flomax 0.4 mg Capsules Holder of Approved Application Boehringer Ingelheim

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Change in ANDA ownership

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED N/A THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☒ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify)* Change in ANDA ownership

CERTIFICATION

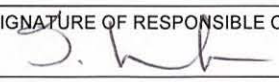
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Princeton, NJ 08540	(609) 627-8885 (Direct) (609) 627-8500 (General)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: September 30, 2008
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Sandoz Inc.	October 23, 2009
TELEPHONE NO. *(Include Area Code)*	FACSIMILE *(FAX)* Number *(Include Area Code)*
(609) 627-8885 (Direct)/(609) 627-8500 (General)	(609) 395-2792
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 506 Carnegie Center Suite 400, Princeton, NJ 08540	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

(b) (4)

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

N/A

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

N/A

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☒	20. OTHER *(Specify) change in ANDA ownership applicant*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
S. Rao	Srinivasa S. Rao, Pharm.D Director, Regulatory Affairs	October 23, 2009

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400, Princeton, NJ 08540	(609) 627-8885 (Direct) / (609) 627-8500 (General)

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Shalin Jani
Regulatory Affairs

Sandoz Inc.
Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel +1 609 627 5214
Fax +1 609 395 2792

SANDOZ

March 11, 2009

Gary J. Buehler
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

-UNSOLICITED AMENDMENT-

RE: ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg
ANDA 77-575

Dear Mr. Buehler:

We submit herewith, an Unsolicited Amendment to ANDA 77-575 for Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg and 80 mg. Please note that a revised manufacturing process is presented for your review and approval. Additionally, reference is made to the deficiency letter from the Division of Bioequivalence, dated January 2, 2008. Included herein is a complete response to the above mentioned deficiency letter. We have performed a new bioequivalence study (fasted state) in support of the response to the bioequivalence deficiency letter. A corresponding Bioequivalence Amendment containing this identical submission will be sent concurrently to the Division of Bioequivalence for their review and approval.

This submission is being provided electronically in ANDA format in line with the original ANDA submission on 1 DVD. An index of the submission has been provided for ease of review.

Please do not hesitate to contact myself at (609) 627-5214 or alternatively, Srinivasa S. Rao, Pharm.D., at (609) 627-8885, if there are any questions regarding this submission.

Sincerely,

Shalin Jani
Regulatory Affairs
Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: August 31, 2005
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Lek Pharmaceuticals d.d.	3/11/09
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
+386 1 580 33 32	+386 1 568 13 66

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*
VEROVSKOVA 57, 1526 LJUBLJANA
SLOVENIA

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
Srinivasa S. Rao, Pharm. D.
Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: +1 609-627-8885
Fax: +1 609 395 2792

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-575

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Atorvastatin Calcium Tablets 10 mg,20 mg,40 mg, 80 mg	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
[R-(R*,R*)]-2-(4-fluorophenyl)-ß,δ-dihoydroxy-5-(1-methylethyl)-3-phenyl-4[(phenylamino)carbonyl]-H-pyrrole-1-heptanoic acid, calcium salt (2:1)

CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Tablets	10 mg, 20 mg, 40 mg, 80 mg	Oral

(PROPOSED) INDICATION(S) FOR USE:
Cholesterol Lowering

APPLICATION INFORMATION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug LIPITOR (atorvastatin calcium) Tablets Holder of Approved Application PFIZER

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
UNSOLICITED AMENDMENT

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

NONE

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

NONE

This application contains the following items: *(Check all that apply)*	
☒	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☒	4. Chemistry section
☒	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☒	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☒	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D. Director, Regulatory Affairs	3/11/09

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400 Princeton, NJ 08540	(609) 627-8885

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CDER, HFD-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Shalin Jani
Regulatory Affairs

Sandoz Inc.
Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel +1 609 627 5214
Fax +1 609 395 2792

SANDOZ

March 11, 2009

Gary J. Buehler
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

-BIOEQUIVALENCE AMENDMENT-

RE: ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg
ANDA 77-575

Dear Mr. Buehler:

We submit herewith, an Bioequivalence Amendment to ANDA 77-575 for Atorvastatin Calcium Tablets 10 mg, 20 mg, 40 mg and 80 mg. Reference is made to the deficiency letter from the Division of Bioequivalence, dated January 2, 2008. Included herein is a complete response to the above mentioned deficiency letter. We have performed a new bioequivalence study (fasted state) in support of the response to the bioequivalence deficiency letter. Additionally, a revised manufacturing process is presented. A corresponding Unsolicited Amendment containing this identical submission will be sent concurrently to the Division of Chemistry for their review and approval.

This submission is being provided electronically in ANDA format in line with the original ANDA submission on 1 DVD. An index of the submission has been provided for ease of review.

Please do not hesitate to contact myself at (609) 627-5214 or alternatively, Srinivasa S. Rao, Pharm.D., at (609) 627-8885, if there are any questions regarding this submission.

Sincerely,

Shalin Jani
Regulatory Affairs
Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: August 31, 2005
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Lek Pharmaceuticals d.d.	3/11/09
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
+386 1 580 33 32	+386 1 568 13 66
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* **IF APPLICABLE**
VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	Srinivasa S. Rao, Pharm. D. Director, Regulatory Affairs 506 Carnegie Center, Suite 400 Princeton, NJ 08540 Phone: +1 609-627-8885 Fax: +1 609 395 2792

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-575

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Atorvastatin Calcium Tablets 10 mg,20 mg,40 mg, 80 mg	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
[R-(R*,R*)]-2-(4-fluorophenyl)-ß,δ-dihoydroxy-5-(1-methylethyl)-3-phenyl-4[(phenylamino)carbonyl]-H-pyrrole-1-heptanoic acid, calcium salt (2:1)

CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Tablets	10 mg, 20 mg, 40 mg, 80 mg	Oral

(PROPOSED) INDICATION(S) FOR USE:
Cholesterol Lowering

APPLICATION INFORMATION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug LIPITOR (atorvastatin calcium) Tablets Holder of Approved Application PFIZER

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
BIOEQUIVALENCY AMENDMENT

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

NONE

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

NONE

This application contains the following items: *(Check all that apply)*	
☒	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☒	4. Chemistry section
☒	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☒	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☒	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

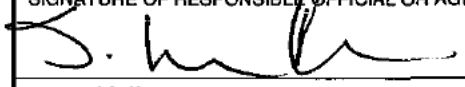
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE:
	Srinivasa S. Rao, Pharm.D. Director, Regulatory Affairs	3/11/09

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
506 Carnegie Center, Suite 400 Princeton, NJ 08540	(609) 627-8885

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CDER, HFD-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

BIOEQUIVALENCY AMENDMENT

ANDA 77-575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (240-276-9327)

APPLICANT: Lek Pharmaceuticals d.d. TEL: 609-627-8854

ATTN: Carmelle Lucas, Ph.D. FAX: 609-395-2792

FROM: Beth Fabian-Fritsch PROJECT MANAGER: (240) 276-8782

Dear Madam:

This facsimile is in reference to the bioequivalency data submitted on April 3, 2007, pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

The Division of Bioequivalence has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached 2 pages. This facsimile is to be regarded as an official FDA communication and unless requested, a hard-copy will not be mailed.

You should submit a response to these deficiencies in accord with 21 CFR 314.96. Your amendment should respond to all the deficiencies listed. **Facsimiles or partial replies will not be considered for review**, nor will the review clock be reactivated until all deficiencies have been addressed. Your cover letter should clearly indicate that the response is a "Bioequivalency Amendment" and clearly identify any new studies (i.e., fasting, fed, multiple dose, dissolution data, waiver or dissolution waiver) that might be included for each strength. We also request that you include a copy of this communication with your response. Please submit a copy of your amendment in both an archival (blue) and a review (orange) jacket. Please direct any questions concerning this communication to the project manager identified above.

SPECIAL INSTRUCTIONS:

In an effort to improve document flow and availability to review staff, please submit your response in electronic PDF format, with a signed cover letter and 356h form.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

BIOEQUIVALENCE DEFICIENCIES

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. Your study uses a two-treatment, three-period replicated crossover design. Your statistical analysis which did not include the subject-by-formulation interaction term is therefore not appropriate. In your analysis, the 90% confidence intervals were computed using the wrong error term. Our analysis, by modifying your proc mixed statements (to include the term subj*trt(seq)) and using the full dataset (i.e., all three periods), showed a statistically significant subject-by-formulation interaction (p = 0.0161 per REML fitting method) and 90% confidence intervals of 98.47% - 126.70% for Cmax. This result is similar to that obtained using the method described in the guidance (which also allows for the possibility of subject-by-formulation interaction).

2. Furthermore, your analysis, based on only the data from periods 1 and 2, 'Per(1,2)', is not acceptable. Using dataset 'Per(1,2)' is not an acceptable scenario due to artificially deleting the measures from the third period with no scientific reason. In addition, if using dataset 'Per(1,2)' is to be considered, then dataset 'Per (1,3)' should be checked too. The upper bound of the 90% confidence interval for dataset 'Per(1,3)' is 132.131% which is greater than the 125% bioequivalence limit.

3. Regarding your statement that " Therefore, the same approach with regards to the intra-variability estimation and SAS codes as for a 2-way crossover design had been identified *a priori* as the method of choice before the conduct of the study, and clearly mentioned in section 10.2.4 of the protocol.", please note that the agency would not accept the results of an inappropriate analysis based on an unsuitable statistical analysis method mentioned in the protocol.

Therefore, your fasted study AA05474 remains unacceptable since the 90% confidence intervals for atorvastatin Cmax are 98.5% - 126.7%, outside the acceptable limit of 80%-125%.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA# 77-575

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Barbara Davit
12/31/2007 12:44:44 PM
Signing for Dale P Conner

Baarbara LoPiccolo
Regulatory Affairs

Sandoz Inc.
Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel: 609 627 8853
Fax : 609 395 2792

SANDOZ

September 26, 2007

Office of Generic Drugs
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20885

ORIG AMENDMENT

-MINOR AMENDMENT-

RE: ATORVASTATIN CALCIUM TABLETS
10 mg, 20 mg, 40 mg and 80 mg
ANDA 77-575
Response to deficiency letter dated April 25, 2007

Dear Sir or Madam:

On behalf of Lek Pharmaceuticals d.d., we are submitting a Minor Amendment to our pending Abbreviated New Drug Application for **ATORVASTATIN CALCIUM TABLETS 10 mg, 20 mg, 40 mg and 80 mg (ANDA 77-575)**.

This amendment is in response to a minor deficiency letter dated April 25, 2007 that we received from the FDA.

The firm has submitted an additional copy of this Minor Amendment to the Office of Generic Drugs, Food and Drug Administration. We hereby certify that this additional copy (field copy) is a true copy of the Archival and Review copies submitted.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid postage envelope.

Sincerely,

Barbara LoPiccolo
Regulatory Affairs

RECEIVED
SEP 27 2007
OGD

MINOR AMENDMENT

ANDA 77-575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (301-594-0320)

APPLICANT: Lek Pharmaceuticals d.d. TEL: 609-627-8854

ATTN: Carmelle Lucas, Ph.D. FAX: 609-395-2792

FROM: Leigh Ann Matheny PROJECT MANAGER: (301) 827-5727

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated February 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to your amendment dated October 2, 2006.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (__2__ pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. The designation as a MINOR AMENDMENT should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

36. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals d.d.

DRUG PRODUCT: Atorvastatin Tablets 10 mg, 20 mg, 40 mg and 80 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:



B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. The bioequivalence section of your application is under review and you will be notified separately of any deficiencies.

2. Please provide all available room temperature stability data for our evaluation.

Sincerely yours,

{See appended electronic signature page}

Vilayat A. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Devinder Gill
4/25/2007 01:12:51 PM
for Vilayat Sayeed, Ph.D.

Barbara LoPiccolo
Regulatory Affairs

Sandoz Inc.
Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel +1 609 627 8853
Fax +1 609 395 2792

SANDOZ

Office of Generic Drugs
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20885

ORIG AMENDMENT AB

April 3, 2007

ORIGINAL

-EXPIDITED REVIEW REQUESTED-

RE: BIOEQUIVALENCY AMENDMENT to ANDA 77-575 for ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg

Dear Sir/Madam:

On behalf of Lek Pharmaceuticals d.d., we are submitting a Bioequivalency Amendment to ANDA 77-575 for Atorvastatin Calcium. Please reference the enclosed letter from Lek for details of the updates being made.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid postage envelope.

Sincerely,

Barbara LoPiccolo
Regulatory Affairs

Enclosures

RECEIVED
APR 04 2007
OGD / CDER

cc: Lek Pharmaceuticals d.d. (Mateja Pfajfar)

BIOEQUIVALENCY AMENDMENT

ANDA 77-575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (301-594-0320)

APPLICANT: Lek Pharmaceuticals d.d. TEL: 732-355-4053

ATTN: Barbara LoPiccolo FAX: 609-395-2792

FROM: Beth Fabian-Fritsch PROJECT MANAGER: (240) 276-8782

Dear Madam:

This facsimile is in reference to the bioequivalency data submitted on March 6, 2006, pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg.

The Division of Bioequivalence has completed its review of the submission(s) referenced above and has identified deficiencies which are presented on the attached 2 pages. This facsimile is to be regarded as an official FDA communication and unless requested, a hard-copy will not be mailed.

You should submit a response to these deficiencies in accord with 21 CFR 314.96. Your amendment should respond to all the deficiencies listed. **Facsimiles or partial replies will not be considered for review**, nor will the review clock be reactivated until all deficiencies have been addressed. Your cover letter should clearly indicate that the response is a "Bioequivalency Amendment" and clearly identify any new studies (i.e., fasting, fed, multiple dose, dissolution data, waiver or dissolution waiver) that might be included for each strength. We also request that you include a copy of this communication with your response. Please submit a copy of your amendment in both an archival (blue) and a review (orange) jacket. Please direct any questions concerning this communication to the project manager identified above.

SPECIAL INSTRUCTIONS:

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

BIOEQUIVALENCE DEFICIENCIES

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals, d.d.

DRUG PRODUCT: Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg

The Division of Bioequivalence has completed its review of your submission(s) acknowledged on the cover sheet. The following deficiencies have been identified:

1. We have reviewed the SAS codes used in your data analysis. Your statistical model is different from that recommended in the agency's statistical guidance "Statistical Approaches to Establishing Bioequivalence", issued in January 2001 for a replicated crossover study. Based on the agency's analysis, your atorvastatin Cmax in the fasting bioequivalence study AA05474 did not meet BE acceptance criterion of 80-125%. The 90% confidence interval calculated by the agency was 98.5-126.7%.

2. The results of one of the active metabolites, para-hydroxyatorvastatin, did not support that your test product is comparable with the reference product. Please explain why DBE should consider your test product is bioequivalent to the reference product based on these data.

Sincerely yours,

{See appended electronic signature page}

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Barbara Davit
3/12/2007 05:40:29 PM
Signing for Dale P Conner

FDA FAX

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (301-594-0320)

TO: Sandoz Inc. TEL: 609-627-8854
US Agent for Lek Pharmaceutical and Chemical Company d.d.

ATTN: Carmelle Lucas, Ph.D. FAX: 609-395-2792

Dear Madam:

This facsimile is in reference to your abbreviated new drug applications submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act.

Pages (including cover): 5

SPECIAL INSTRUCTIONS:

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

Sandoz Inc. US Agent for Lek Pharmaceutical and Chemical Company d.d.
Attention: Carmelle Lucas
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Dear ANDA Holder/Applicant:

We are writing to you as the sponsor of pending abbreviated new drug application(s) (ANDAs) supported by bioequivalence studies in which the bioanalytical analysis was conducted by (b) (4) ((b) (4) at the (b) (4) ((b) (4)) and (b) (4) sites in (b) (4).

FDA has conducted several comprehensive inspections of bioequivalence studies conducted by (b) (4) since (b) (4) The findings of these inspections raise significant concerns about the validity of the reported results of these analytical studies conducted in support of drug applications for marketing. Our findings from these inspections include, but are not limited to, the following:

- Failure to conduct a systematic and thorough evaluation to identify and correct sources of contamination.
- Failure to investigate anomalous results.
- Lack of assay reproducibility between original and repeat results.
- Assay accuracy not assured under the conditions of sample processing.
- Biased manipulation of study data resulting in the acceptance of failed runs.
- Failure to demonstrate the accuracy of analytical methods with appropriate validation experiments and documentation.

As a result of these findings, (b) (4) agreed to conduct an audit of data from all its bioequivalence studies generated from (b) (4). However, FDA identified significant deficiencies with the (b) (4) audit during its most recent inspection. Thus, serious questions remain about the validity of bioequivalence data generated by (b) (4) in studies during this time period that have not been inspected by FDA, including the studies you have submitted in support of your applications. In view of these findings, FDA is informing holders of pending ANDA(s) of these issues and would like to know what steps are being taken by you to assure the accuracy of data submitted in these applications and confirm the validity of (b) (4) analytical studies that

were conducted from (b) (4) and subsequently submitted to the FDA. Accordingly, with respect to these studies submitted in your application(s), we request that you do one of the following, in order of FDA preference:

1. Repeat the bioequivalence studies.

2. Re-assay the samples at a different bioanalytical facility. For this option, the integrity of the original samples must be demonstrated for the frozen storage period.

3. Commission a scientific audit by a qualified independent expert, who is knowledgeable in the area of bioequivalence studies and bioanalytical data, and selected by your company rather than by (b) (4) to verify the results obtained by (b) (4)

In addition, because one of the agency's significant findings for the inspected (b) (4) studies was the presence of anomalous results, we are requesting for all of the above options that the blood/plasma level results obtained in the studies be compared to any published literature or other relevant information that is publicly available. If you are unable to complete one of these options within the recommended six month time frame, please inform us of the reason(s) and your estimated time of completion.

If you choose to conduct an audit, we request that the completed audit reports be maintained at your site. If the audit finds the study acceptable, we request that you submit a certification to your application that formally attests in writing to the validity of the results obtained by (b) (4) upon which your application relies. If the audit finds the study to be unacceptable, you should either repeat the bioequivalence study and submit the information within 6 months of the completed audit or withdraw the application. Please note that these audits would also be subject to validity assessment by the agency upon submission.

The audit criteria provided below includes, but is not limited to, examples of areas that should be evaluated.

- The audit criteria for reviewing pre-study validation data should address whether accuracy and stability were demonstrated with appropriate validation experiments and documentation, and under the conditions of sample processing used for the analysis of samples from study subjects.

- The audit criteria for reviewing the results of the bioequivalence studies should address whether anomalous results were investigated and issues related to contamination were identified and corrected. It should also determine if a comparison of all available original and repeat results demonstrated assay reproducibility, and whether analytical runs were accepted in accordance with established procedures and without bias.

The new bioequivalence data or the re-analysis of the existing data should be submitted to your application as an amendment. If the new information does not support a finding of bioavailability/bioequivalence, the FDA may refuse to approve your application(s). Please find

attached the list of your pending applications with studies conducted at (b) (4) during the specified time period.

If you have any questions regarding this letter, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Sandoz Inc. US Agent for Lek Pharmaceutical and Chemical Company d.d. ANDAs with studies conducted at (b) (4)

76-515 Omeprazole
76-859 Amlodipine
77-424 Losartan
77-438 Levofloxacin
77-575 Atorvastatin

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Gary Buehler

1/10/2007 08:02:44 AM

Lalitha Subramanian
Regulatory Affairs

Sandoz Inc.
Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Tel +1 609 627 8859
Fax +1 609 395 2792

SANDOZ

October 2, 2006

ORIG AMENDMENT
N-AM

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

RECEIVED
OCT 0 3 2006
OGD / CDER

-MINOR AMENDMENT FIELD COPY-

RE: ATORVASTATIN CALCIUM TABLETS
10 mg, 20 mg, 40 mg and 80 mg
ANDA 77-575
Response to deficiency letter dated March 13, 2006

Dear Sir or Madam:

This is to inform you that we have submitted to the Office of Generic Drugs a Minor Amendment to our pending Abbreviated New Drug Application (**ANDA # 77-575**) for **ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg and 80 mg,** as required under the final rule published in the Federal Register, Volume 58, Number 172, dated 09/08/93.

As the proposed manufacturing site, LEK Pharmaceuticals d.d., is located overseas the firm is submitting a "Field Copy" to the Office of Generic Drugs.

We hereby certify that the field copy is a true copy of the Technical Section as described in § 314.50 (d) (1) contained in the Archival and Review copies of the application.

Sincerely,

Lalitha Subramanian
Regulatory Affairs

SANDOZ

Barbara LoPiccolo
Drug Regulatory
Affairs Associate

Sandoz Inc.
506 Carnegie Center
Princeton, NJ 08540

Tel 609-627-8853
Fax 609-395-2792

July 10, 2006

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

- LABELING AMENDMENT -

Re: ATORVASTAIN CALCIUM TABLETS 10 mg, 20 mg, 40 mg, and 80 mg
ANDA # 77-575
Response to FDA Letter Dated July 5, 2006

Dear Sir or Madam:

Reference is made to your correspondence dated July 5, 2006 regarding deficiencies relating to **ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg (ANDA # 77-575).** Enclosed herewith is a LABELING AMENDMENT addressing the deficiencies noted in your letter.

We have attached an electronic version of the Patient Information Leaflet on CD to the Archival copy of this submission.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self addressed stamped envelope.

For any communication regarding this ANDA application, please contact Dr. Carmelle Lucas, at (609) 627-8854 (phone) or (609) 395-2792 (facsimile).

Sincerely,

Barbara LoPiccolo
Regulatory Affairs

SANDOZ

Barbara LoPiccolo
Drug Regulatory
Affairs Associate

Sandoz Inc.
2400 Route 130 North
Dayton, NJ 08810

Tel 732-355-4053
Fax 609-395-2792

June 8, 2006

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

- LABELING AMENDMENT -

Re: ATORVASTAIN CALCIUM TABLETS 10 mg, 20 mg, 40 mg, and 80 mg
ANDA # 77-575
Response to FDA Letter Dated December 7, 2005

Dear Sir or Madam:

Reference is made to your correspondence dated December 7, 2005 regarding deficiencies relating to **ATORVASTATIN CALCIUM TABLETS, 10 mg, 20 mg, 40 mg, and 80 mg (ANDA # 77-575).** Enclosed herewith is a LABELING AMENDMENT addressing the deficiencies noted in your letter.

We have attached an electronic version of the Package Insert, Patient Information Leaflet, and Container labeling on CD, to the Archival copy of this submission.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self addressed stamped envelope.

For any communication regarding this ANDA application, please contact Dr. Carmelle Lucas, at (732) 355-4083 (phone) or (609) 395-2792 (facsimile).

Sincerely,

Barbara LoPiccolo

Barbara LoPiccolo
Regulatory Affairs

MINOR AMENDMENT

ANDA 77-575

MAR 13 2006

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (301-594-0320)

APPLICANT: Lek Pharmaceuticals d.d.

TEL: 732-355-4083

ATTN: Carmelle Lucas, Ph.D.

FAX: 609-395-2792

FROM: Leigh Ann Matheny

PROJECT MANAGER: (301) 827-5727

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated February 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg.

Reference is also made to your amendments dated October 12, 2005, November 15, 2005, December 19, 2005, January 13, 2006 and March 6, 2006.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (__2__ pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. The designation as a MINOR AMENDMENT should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

3/10/06

36. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals d.d.

DRUG PRODUCT: Atorvastatin Tablets 10 mg, 20 mg, 40 mg and 80 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

(b) (4)

[redacted]

(b) (4)



B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. The bioequivalence section of your application is under review and you will be notified separately of any deficiencies.

2. Please provide all available room temperature stability data for our evaluation.

3. The safety review of (b) (4) you have provided is pending review. After the review is completed, any deficiencies found will be communicated to you separately.

Sincerely yours,

DSG III

Vilayat A. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research

Barbara LoPiccolo
Regulatory Affairs

Sandoz Inc.
2400 Route 130 North
Dayton, NJ 08810

Tel +1 732 355 4053
Fax +1 609 395 2792

SANDOZ

ORIGINAL

FedEx OVERNIGHT MAIL

Office of Generic Drugs
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20885

ORIG AMENDMENT
N/AB

March 6, 2006

RE: BIOEQUIVALENCY AMENDMENT to ANDA 77-575 for ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg

Dear Sir/Madam:

On behalf of Lek Pharmaceuticals d.d., we are submitting a Bioequivalency Amendment to ANDA 77-575 for Atorvastatin Calcium. Please reference the enclosed letter from Lek for details of the updates being made.

Included in this submission are the following:

1. CD contianing SAS codes, input and output files is attached to the front cover of the Archival copy of this submission.

2. Hard copy of the information contained on the CD

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid postage envelope.

Sincerely,
Sandoz Inc.

Barbara LoPiccolo
Regulatory Affairs

Enclosures cc: Lek Pharmaceuticals d.d. (Mateja Pfajfar)

RECEIVED
MAR 0 7 2006
OGD / CDER

SANDOZ

Barbara LoPiccolo
Regulatory Affairs Associate

Sandoz Inc.
Regulatory Affairs
2400 Route 130 North
Dayton, NJ 08810

Tel +1 732 355 4053
Fax +1 609 395 2792

January 13, 2006

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855

- TELEPHONE AMENDMENT -

RE: ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg
ANDA 77-575

Dear Mr. Steve Mazzella:

On behalf of Lek Pharmaceuticals d.d., we are submitting a Telephone Amendment for **ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg (ANDA 77-575)** as required under 21 CFR 314.96.

As a result of a communication between Mr. Steve Mazzella and Barbara LoPiccolo on January 5, 2006 the following information is included herewith:

SAS data for the Fasted Bioequivalence Study AA05474
SAS data for the Fed Bioequivalence Study AA05473

Hard copy will include a CD with the tables.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid postage envelope.

Sincerely,
Sandoz Inc.

Barbara LoPiccolo
Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: August 31, 2005
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Lek Pharmaceuticals d.d.	12/19/05
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE** *(FAX)* **Number** *(Include Area Code)*
+38 6 1 580 33 32	+386 1 568 13 66
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* **IF APPLICABLE**
VEROVSKOVA 57, 1526 LJUBLJANA SLOVENIA	Dr.Carmelle Lucas, Head of Regulatory Affairs 2400 Route 130 North Dayton, NJ 08810-1519 Phone: +1 732 355 4083 Fax: +1 609 395 2792

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* 77-575

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Atorvasta tin Calcium Tablets 10 mg,20 mg,40 mg, 80 mg	NONE

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*
[R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihoydroxy-5-(1-methylethyl)-3-phenyl-4[(phenylamino)carbonyl]-H-pyrrole-1-heptanoic acid, calcium salt (2:1)

CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Tablets	10 mg, 20 mg, 40 mg, 80 mg	Oral

(PROPOSED) INDICATION(S) FOR USE:
Cholesterol Lo wering

APPLICATION INFORMATION

APPLICATION TYPE *(check one)*
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug LIPITOR (atorvastatin calcium) Tablets Holder of Approved Application PFIZER

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO APENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
TELEPHONE AMENDMENT

PROPOSED MARKETING STATUS *(check one)* ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

NONE

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

NONE

This application contains the following items: *(Check all that apply)*

☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
☐	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☒	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☐	20. OTHER *(Specify)*

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
	Carmelle Lucas, Ph.D. Head of Regulatory Affairs	12/19/05

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
2400 Route 130 North Dayton, nJ 08810	(732) 355-4083

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CDER, HFD-99
5401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Barbara LoPiccolo
Regulatory Affairs Associate

Sandoz Inc.
Regulatory Affairs
2400 Route 130 North
Dayton, NJ 08810

Tel +1 732 355 4053
Fax +1 609 395 2792
Internet: sangita.patankar
@sandoz.com

SANDOZ

ORIG AMENDMENT

N1AM

FedEx OVERNIGHT MAIL

Office of Generic Drugs
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20885

October 12, 2005

RE: MINOR AMENDMENT to ANDA 77-575 for
ATORVASTATIN CALCIUM Tablets 10 mg, 20 mg, 40 mg and 80 mg

Dear Sir/Madam:

On behalf of Lek Pharmaceuticals d.d., we are submitting a Minor Amendment to ANDA 77-575 for Atorvastatin Calcium. Please reference the enclosed letter from Lek for details of the updates being made.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid postage envelope.

Sincerely,

Sandoz Inc.

Barbara LoPiccolo
Regulatory Affairs

Enclosures

cc: Lek Pharmaceuticals d.d. (Mateja Pfajfar)

RECEIVED
OCT 13 2005
OGD/CDER

MINOR AMENDMENT

AUG 3 1 2005

ANDA 77-575

OFFICE OF GENERIC DRUGS, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773 (301-594-0320)

APPLICANT: Sandoz Services, Inc.
U.S. Agent for Lek Pharmaceuticals d.d.

TEL: 303-438-4237

FAX: 303-438-4600

ATTN: Beth Brannan

PROJECT MANAGER: (301) 827-5754

FROM: Thuyanh (Ann) Vu

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated February 11, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Atorvastatin Calcium Tablets, 10 mg , 20 mg, 40 mg and 80 mg.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (2 pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. The designation as a MINOR AMENDMENT should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:
CMC comments

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

AUG 3 1 2005

36. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 77-575 APPLICANT: Lek Pharmaceuticals d.d.

DRUG PRODUCT: Atorvastatin Tablets 10 mg, 20 mg, 40 mg and 80 mg

The deficiencies presented below represent MINOR deficiencies.

A. Deficiencies:

1. Please correct the switched titles (Generic drug and Listed drug) in the comparison table on page 21.



(b) (4)

[redacted]

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. The bioequivalence and labeling sections of your application are under review and you will be notified separately of any deficiencies.

2. A satisfactory compliance evaluation for each of the facilities listed for drug substance and drug product manufacturing and quality control in the application is necessary at the time of the approval.

3. Please provide all available room temperature stability data for our evaluation.

4. The toxicology study data you have provided for Tromethamine is pending review. After the review is completed, any deficiencies found will be communicated to you separately.

Sincerely yours,

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

Beth Brannan, Director
Regulatory Affairs

Sandoz Inc.
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446

Tel +1 303 438-4237
Fax +1 303 438-4600
Internet:
Beth.Brannan@gx.novartis.com

SANDOZ

OVERNIGHT DELIVERY

Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Metro Park North 2, Room 150
7500 Standish Place
Rockville, MD 20855

Patent Amendment

XP

August 26, 2005

RE: ANDA 77-575 Atorvastatin Calcium Tablets 10, 20, 40, and 80 mg

Dear Director:

On behalf of Lek Pharmaceuticals d.d. (Slovenia), Sandoz Inc. is hereby submitting an amendment to ANDA 77-575 Atorvastatin Calcium Tablets 10, 20, 40, and 80 mg in accord with Section 505 (j) of the Federal Food, Drug, and Cosmetic Act; 21 CFR Part 314.96.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed stamped envelope.

Sincerely,

Sandoz Inc.

Sherwood for
Beth Brannan, Director
Drug Regulatory Affairs

Enclosures

BB/ags

RECEIVED
AUG 29 2005
OGD/CDER

SANDOZ

From Beth Brannan

Phone 303 438 4237

Fax 303 438 4600

E-mail beth.brannan@sandoz.com

Patent Amendment

XP

Gary Buehler, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Metro Park North 2, Room 150
7500 Standish Place
Rockville, MD 20855

JUL 14 2005

RE: ANDA 77-575 Atorvastatin Calcium Tablets 10, 20, 40 and 80 mg

Dear Madam or Sir:

On behalf of Lek Pharmaceuticald d.d. (Slovenia), Sandoz Inc.(Broomfield), is hereby submitting this patent amendment to ANDA 77-575 for Atorvastatin Calcium Tablets.

Please note that a field copy is not provided as this is a patent related submission only.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self addressed, prepaid postage envelope.

Sincerely,

SANDOZ INC.

Asherwood for

Beth Brannan
Director, Regulatory Affairs

C: Lek Pharmaceuticals d.d. (A. Vukadin-Skulj, M. Pfajfar)

Sandoz

2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446
Phone 303 466 2400
www.us.sandoz.com

RECEIVED
JUL 15 2005
OGD/CDER

Beth Brannan
Director

Sandoz, Inc.
Regulatory Affairs
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446

Tel +1 303 438 4237
Fax +1 303 438 4600
Internet:
beth.brannan@sandoz.com

SANDOZ

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855
USA

New Correspondence

NEW CORRESP
N/mc

June 17, 2005

RE: New Correspondence, Change of U.S. Agent

Dear Madam or Sir:

Effective June 9, 2005, Sandoz Inc. is hereby notifying you of its intent to act as U.S. Agent for Lek Pharmaceuticals d.d. This change represents a change in U.S. Agent only. All else remains the same.

Please acknowledge receipt of this document by signing and dating the enclosed copy of the cover letter and returning it in the self-addressed, prepaid-postage envelope.

Sincerely,

SANDOZ INC.

Beth Brannan, Director
Regulatory Affairs

BB/AP/ic

RECEIVED
JUN 20 2005
OGD / CDER

lek
a new Sandoz company

Lek Pharmaceuticals d.d.

Verovškova 57
SI - 1526 Ljubljana
Slovenia

Phone: +386 1 580 21 11
Fax: +386 1 568 35 17

Regulatory Affairs

Phone: +386 1 580 33 32
Fax: +386 1 568 13 66

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

MPN II, HFD-600
7500 Standish Place
Rockville, MD20855
USA

MC

No.: 517/05

Date: April 1, 2005

Subject: **TELEPHONE AMENDMENT to ANDA 77-575 for ATORVASTATIN CALCIUM Tablets, 10 mg, 20 mg, 40 mg, 80 mg**

Dear Sirs,

Reference is made to our Abbreviated New Drug Application #77-575 for ATORVASTATIN CALCIUM Tablets, 10 mg, 20 mg, 40 mg, 80 mg of February 11, 2005.
Reference is also made to the telephone conversation of 31 March 2005 between Mr Ian Margand, OGD and Mr Branko Huč, Sandoz Services, Inc.

This Telephone Amendment is being submitted in order to respond to all the questions raised in this telephone conversation.

Enclosed please find 2 originally signed documents of Lek Debarment certifications and Field copy certification. We are sorry for providing only the copies of the above documents. In addition, we noticed that the originally signed Request for exclusion from requirement for environmental impact analysis statement has not been provided either. Therefore, we are attaching also 2 originally signed documents of this request.

RECEIVED
APR 05 2005
OGD/CDER

Should you have any questions concerning this ANDA, please contact:

Mr. Branko Huč
The Vice President of Sandoz Services, Inc.
115 North Third Street - Suite 301
Wilmington NC 28401
Phone: (910) 362 - 0760
Fax: (910) 362 - 0790

or

Headquarters in Ljubljana:

Regulatory Affairs,
Mrs. A. Vukadin - Škulj, Director
Phone: + 386 1 580 3 332, + 386 1 580 2 338
Fax: + 386 1 568 1366

Sincerely yours,

Lek Pharmaceuticals d.d.
Regulatory Affairs

M. Pfajfar
Head of Department

A. Vukadin - Škulj
Director

cc: Mr. Branko Huč, SANDOZ SERVICES, INC.; Mr. M. Žorž, Lek Pharmaceuticals d.d.