CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-702/S028

Trade Name: Lipitor Tablets

Generic Name: atorvastatin

Sponsor: Pfizer, Inc.

Approval Date: November 20, 2001

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APPLICATION NUMBER:
NDA 20-702/S028

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APPLICATION NUMBER:

NDA 20-702/S028

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-028

Pfizer Inc.
Attention: Rita A. Wittich
Vice President, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated August 24, 2001, received August 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin tablets).

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of [redacted] for the drug substance, atorvastatin calcium.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Moore
11/20/01 10:46:02 AM

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APPLICATION NUMBER:

NDA 20-702/S028

CHEMISTRY REVIEW(S)

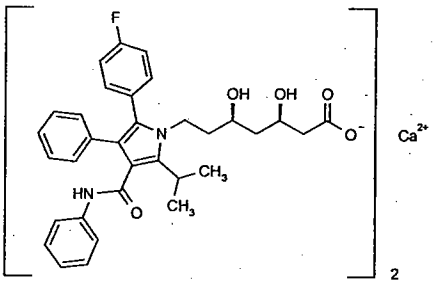
CHEMIST'S REVIEW

1. Organization CDE/HFD-510 Division Of Metabolism And Endocrine Drug Products	**2. NDA #** 20-702 Approved: 17-Dec-1996
3. Name and Address of Applicant Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company 2800 Plymouth Road P.O. Box 1047 Ann Arbor, MI 48106-1047 (313) 966-5000	**4. Supplement** SCS-028 Doc. 24-AUG-2001 Rec. 27-AUG-2001 **5. Name of the Drug** Lipitor Tablets **6. Nonproprietary Name** Atorvastatin Calcium
7. Supplement provides for the addition of [redacted] for the drug substance, atorvastatin calcium.	**8. Amendment** --

9. Pharmacological Category Lipid Modifier. HMG-CoA reductase inhibitor/ Antihyperlipoproteinemic agent.	**10. How Dispensed** Rx	**11. Related** -N. A.-
12. Dosage Form Tablet	**13. Potency** 10-, 20-, 40- and 80-mg	

14. Chemical Name and Structure

Atorvastatin Calcium
$(C_{33}H_{34}FN_2O_5)_2Ca$
FW = 2 x 557.7 + 40.0 = 1155.38 (anhydrous calcium salt)
CAS 134523-03-8
CAS 134523-00-5 (atorvastatin)
FW free acid $C_{33}H_{34}FN_2O_5$ = 558.66
FW calcium salt trihydrate $(C_{33}H_{34}FN_2O_5)_2Ca \cdot 3H_2O$ = 1209.42



[*R*-(*R**,*R**)]-2-(4-flourophenyl)-ß, -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1*H*-pyrrole-1-heptanoic acid calcium salt (2:1)

15. Comments: This CBE-30 days supplement, SCS-028, provides for the addition of an [redacted] for the drug substance, atorvastatin calcium. In support of this supplement the applicant, Pfizer Pharmaceutical Group, provides a complete description of the [redacted] same. **Comparative batch analysis** (3 full batches manufactured [redacted] and 3 commercial batches manufactured according the current procedure) of [redacted] nd atorvastatin calcium (finished drug product) **shows the equivalence of both manufacturing procedures.** The provided CMC information meets the regulatory requirements.

16. Conclusions and Recommendations: The [redacted] is equivalent to the current drug substance manufacturing procedure [redacted] **Issue Approval Letter.**

17. Reviewer Name (and Signature) **Date Completed** 16-OCT-2001

Xavier Ysern, PhD

R/D INITIATED BY

Stephen Moore, PhD
Chemist Team Leader

filename: /nda/20702s28.doc

DISTRIBUTION: Original: NDA 20-702 cc: HFD-510 Division File / MooreS/ SimoneauM/ YsernX

CBE-30 AP

9 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-702
5028

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/s/

Xavier Ysern
10/19/01 11:47:50 AM
CHEMIST

AP

Stephen Moore
10/19/01 04:31:38 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-702/S028

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-028

CBE-30 SUPPLEMENT

Pfizer Inc., Agent for Pfizer Ireland Pharmaceuticals
Attention: Ms. Rita A. Wittich
Vice President, Worldwide Regulatory Strategy
235 East 42nd Street, 150/7/12
New York, N.Y. 10017

Dear Ms. Wittich:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Lipitor (atorvastatin calcium) Tablets
NDA Number:	20-702
Supplement Number:	S-028
Date of Supplement:	August 24, 2001
Date of Receipt:	August 27, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes the following change: To add an [redacted] for the drug substance, atorvastatin calcium.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 26, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be February 27, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 14B19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Margaret Simoneau, R.Ph.
Regulatory Project Manager
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Julie Rhee
8/28/01 09:42:43 AM
Signed for Peggy Simoneau