CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020702, S014

Trade Name: LIPITOR TABLETS

Generic Name: ATORVASTATIN CALCIUM

Sponsor: PARKE-DAVIS PHARMACEUTICAL RESEARCH

Approval Date: 08/28/98

Indication(s): LIPID ALTERING AGENT

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 020702, S014

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling		X		
Medical Review(s)				X
Chemistry Review(s)				X
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative Document(s)/ Correspondence	X			

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020702, S014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-014

AUG 28 1998

Parke-Davis Pharmaceutical Research
Attention: Sharon S. Phillips
Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Phillips:

Please refer to your supplemental new drug application dated April 30, 1998, received May 1, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) Tablets.

We note that this supplement was submitted with final printed labeling (FPL) as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides labeling changes to the ADVERSE REACTIONS and PRECAUTIONS sections of the Lipitor package insert. These changes are:

ADVERSE REACTIONS

Under the subsection entitled "Postintroduction Reports", "anaphylaxis" was added.

PRECAUTIONS

Deletion of the subsection "Other Concomitant Therapy" under PRECAUTIONS, Drug Interactions section.

Your submission stated June 1, 1998, as the implementation date for the changes.

We have completed the review of this supplemental application and it is approved. Please incorporate this change in the final printed labeling for Supplements-003 and -005 which were approved on July 10, 1998, and supersede this supplement.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that

you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

/S/ 12/7/98

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDA 20-702
HFD-510/Div. Files
HFD-510/M. Simoneau
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-102/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-95/DDMS (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/August 7, 1998
Initialed by:J.Temeck for
D.Orloff8.17.98/R.Steigerwalt8.17.98/X.Ysern8.17.98/S.Moore8.17.98/E.Galliers8.24.98
final:Mas8.25.98 8·26·98
filename: 20702.14 /S/

APPROVAL (AP)

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020702, S014

ADMINISTRATIVE DOCUMENTS/CORRESPONDENCE

AUG 17 1998

Labeling Review

APPROVED

Application Number: NDA 20-702/S-014

Name of Drug: Lipitor (Atorvastatin calcium) Tablets

APPEARS THIS WAY ON ORIGINAL

Sponsor: Parke-Davis

Materials Reviewed: July 10, 1998 (S-003 and S-005) last approved labeling and April 30, 1998 final printed labeling.

Background and Summary Description: Supplement-014 was a SPECIAL SUPPLEMENT-CHANGES BEING EFFECTED. The changes were to add anaphylaxis to the ADVERSE REACTIONS section under the subsection entitled "Postintroduction Reports" and the deletion of the subsection "Other Concomitant Therapy" under PRECAUTIONS, Drug Interactions section.

The last approved draft labeling was accepted July 10, 1998 (supplements 3 and 5) which have incorporated the above noted changes. For supplement-014, the reviewing team has accepted the labeling changes in their submission dated April 30, 1998 (Parke-Davis #0155G026).

Medical Team Leader /S/ for David DeCoff 8/17/98

Pharmacology Team Leader /S/ 8/17/98

Chemistry Reviewer /S/ 17-AUG-1998

Chemistry Team Leader /S/ 8/17/98

Chief, Project Management Staff /S/ 8/21/98

Project Manager /S/ 8/17/98

cc:NDA 20-702/S-014
Div Files

APPEARS THIS WAY ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-014

MAY 22 1998

Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Attention: Sharon S. Phillips
Senior Manager, Worldwide Regulatory Affairs

Dear Ms. Phillips:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Lipitor(Atorvastatin Calcium) 10/20/40 MG
NDA Number:	20-702
Supplement Number:	S-014
Date of Supplement:	April 30, 1998
Date of Receipt:	May 01, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on June 30, 1998, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-702/S-014
HFD-510/Div. Files
HFD-510/CSO/M. Simoneau

filename: C:\DATA\WPFILES\20702ACK

SUPPLEMENT ACKNOWLEDGEMENT

201 Tabor Road Phone 201-540-2000
Morris Plains, NJ
07950

NDA NO. 20-702 REF. NO. 64
NDA SUPPL FOR SLR

PARKE-DAVIS
People Who Care

NDA SUPPLEMENT

April 30, 1998

NDA 20-702
Ref. No. 64
Lipitor® (atorvastatin calcium) Tablets

Re: Labeling:
SPECIAL SUPPLEMENT-
CHANGES BEING EFFECTED

Accepted
/S/
6/26/98

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine
Drug Products (HFD-510)
Center for Drug Evaluation and Research
Office Of Drug Evaluation II
Attention: Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

/S/
6/25/98

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAY 0 1 1998
HFD-510

Dear Dr. Sobel:

Reference is made to our approved NDA 20-702 for Lipitor® (atorvastatin calcium) Tablets.

We have revised the package insert labeling for Lipitor in accordance with 21 CFR 314.70(c) (2) (i); to add anaphylaxis to the ADVERSE REACTIONS section under the subsection entitled "Postintroduction Reports". This adverse reaction has been identified by our post-marketing safety surveillance database. Supporting documentation for the addition of anaphylaxis is included in this submission as Attachment 1.

In addition, we have also deleted the subsection "Other Concomitant Therapy" under PRECAUTIONS, Drug Interactions as per an FDA, March 2, 1998 FAX regarding class labeling for HMG-CoA reductase inhibitors which requested deletion of this section at the next printing.

Twenty copies of the final printed labeling, identified by the specification number 0803G026, reflecting the above revisions are provided in Attachment 2. We expect to implement this revised labeling on June 1, 1998.

If you have any questions or require any additional information, please contact me at 973/540-2920 or by FAX at 973/540-5972.

Sincerely,

Sharon Phillips

Sharon S. Phillips
Senior Manager
Worldwide Regulatory Affairs
Advertising and Labeling

SP\sv\rm
t:\nda\20-702\043098-64

Attachments