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

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

/s/
Stephen Moore
11/20/01 10:46:02 AM
<table>
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<th>1. Organization</th>
<th>CDE/HFD-510 Division Of Metabolism And Endocrine Drug Products</th>
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<tr>
<td>2. NDA # 20-702</td>
<td>Approved: 17-Dec-1996</td>
</tr>
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</table>
| 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 |
| 5. Name of the Drug | Lipitor Tablets |
| 6. Nonproprietary Name | Atorvastatin Calcium |
| 7. Supplement provides for the addition of | ~ Amendment |
| for the drug substance, atorvastatin calcium. |
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_{37}H_{44}FN_{2}O_{8})Ca  
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_{37}H_{44}FN_{2}O_{8} = 558.66  
FW calcium salt trihydrate (C_{37}H_{44}FN_{2}O_{8})_{2}Ca·3H_{2}O = 1209.42  
(R-(R^*,R^*))-2-(4-flourophenyl)-β, -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt (2:1) |
| 15. Comments | This CBE-30 days supplement, SCS-028, provides for the addition of an  
for the drug substance, atorvastatin calcium. In support of this supplement the applicant, Pfizer  
Pharmaceutical Group, provides a complete description of the  

same. Comparative batch analysis (3 full batches manufactured  
and 3 commercial batches manufactured according the current procedure) of  
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 is equivalent to the current drug  
substance manufacturing procedure  
Issue Approval Letter. |
| 17. Reviewer Name (and Signature) | Xavier Ysern, PhD |
| Date Completed | 16-OCT-2001 |

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  

NDA 20-702 SCS-028 CMC Review Page 1 of 10
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☑️ § 552(b)(4) Trade Secret / Confidential

☐ § 552(b)(4) Draft Labeling

☐ § 552(b)(5) Deliberative Process
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/s/

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

AP

Stephen Moore
10/19/01 04:31:38 PM
CHEMIST
NDA 20-702/S-028

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 \underline{}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}_{\underline{ }}\text{ 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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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