CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-702/S-035

Trade Name: Lipitor

Generic Name: (atorvastatin calcium)

Sponsor: Pfizer, Inc.

Approval Date: July 2, 2002
CONTENTS

Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Item</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Approvable Letter</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>X</td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacology/ Biopharmaceutics Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td>X</td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-702/S-035

APPROVAL LETTER
NDA 20-702/S-035

Pfizer Ireland Pharmaceuticals
Attention: Christopher A. Graham
Director, Worldwide Regulatory Strategy
235 East 42nd Street, 150/7/12
New York, NY 10017

Dear Mr. Graham:


This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an / 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
7/2/02 04:59:57 PM
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-702/S-035

CHEMISTRY REVIEW(S)
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**
   Pfizer Ireland Pharmaceuticals
   Pottery Road
   Dun Laoghaire
   County Dublin
   Ireland

4. **Supplement**  SCS-035

5. **Name of the Drug**
   Lipitor Tablets

6. **Nonproprietary Name**
   Atorvastatin Calcium

7. **Supplement provides for the addition of an**
   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

    \[
    (C_{33}H_{34}FN_{2}O_{5})_{2}Ca
    \]

    FW = 2 x 557.7 + 40.0 = 1155.38 (anhydrous calcium salt)
    CAS 134152-03-8
    CAS 134152-00-5 (atorvastatin)
    FW free acid C_{33}H_{34}FN_{2}O_{5} = 558.66
    FW calcium salt trihydrate (C_{33}H_{34}FN_{2}O_{5})_{2}Ca \cdot 3H_{2}O = 1209.42

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

15. **Comments:** This Changes Being Effecte 30 Days Supplement provides an

16. **Conclusions and Recommendations:** The proposed viewpoint this supplement can be approved.

17. **Reviewer Name (and Signature)**
    Xavier Ysern, PhD

    **Date Completed:** 06-JUN-2002

    **R/D Initiated by**
    Stephen Moore, PhD
    Chemist Team Leader

    **Filename:** nda/20702s35.doc

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1. Authorized USA Agent: Pfizer Inc., 235 East 42nd Street, 2800 Plymouth Road, New York, NY 10017  phone: (212) 733-4394
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/s/

Xavier Yserrn
6/24/02 02:13:49 PM
CHEMIST

Stephen Moore
7/1/02 01:30:49 PM
CHEMIST
APPLICATION NUMBER:
20-702/S-035

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
NDA 20-702/S-035

CBE-30 SUPPLEMENT

Pfizer, Inc., Agent for Pfizer Ireland Pharmaceuticals
Attention: Rita A. Wittich
Vice President, Worldwide Regulatory Strategy
235 East 42nd Street 150/7/12
New York, NY 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-035

Date of Supplement: May 14, 2002

Date of Receipt: May 15, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes to add an

of 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 July 14, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 15, 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
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
Office of Drug Evaluation II
Center for Drug Evaluation and Research
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/s/

Margaret Simoneau
5/28/02 01:40:08 PM