

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-702/S025

ADMINISTRATIVE DOCUMENTS



Application #(s): NDA 20-702/S-025

Document Type: Supplement Letter

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COMIS Decision:

Drafted by: Mas/March 21, 2001

Revised by:

Initialed by: M.Parks 3.21 and 28, 2001/ E. Galliers 3.21.28 and 29, 2001/Mike Jones 3.21 and 3.28.2001.

Finalized: Mas 3.29.01

Filename:

DFS Key Words:

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Linking Instructions: Link the outgoing letter to the initial submission of the supplement or the associated RS, AR, or FO coded incoming document for the supplement.



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NDA 20-702/S-025

Parke-Davis Pharmaceutical Research, Agent for
Warner-Lambert Export, Limited
Attention: John R. Kirk
Director, Worldwide Regulatory Affairs
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Mr. Kirk:

Please refer to your pending August 10, 2000, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Lipitor (atorvastatin calcium) Tablets.

We have received the October 20, 2000, amendment to your pending supplemental new drug application (S-025) in which you have deleted _____
_____ This supplement, as amended, proposes the addition of a Geriatric Use subsection.

Please note that a claim regarding _____ is considered a separate change from the addition of a Geriatric Use subsection. Therefore, if you wish to pursue the _____ we would expect submission of a separate supplement per the _____ Act. In addition, we would expect a user fee for the _____ supplement because clinical data would be required for approval.

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

Sincerely,

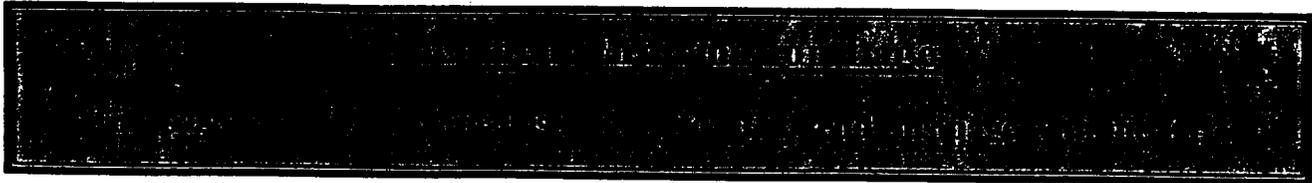
{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

/s/

Mary Parks
3/29/01 03:04:58 PM
For Dr. Orloff

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Application #(s): NDA 20-702/S-025

Document Type: NDA IR

COMIS Decision: I

Drafted by: Mas 4.6.01

Revised by:

Initialed by: M. Parks 4.6.01

Finaled: M. Simoneau (4.6.01)

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Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II

FACSIMILE TRANSMITTAL SHEET

DATE: April 6, 2001

To: Mr. John Kirk	From: Margaret Simoneau
Company: Parke-Davis Pharmaceutical Research	Division of Division of Metabolic and Endocrine Drug Products
Fax number: 734-622-2856	Fax number: (301) 443-9282
Phone number: 734-662-7783	Phone number: (301) 827-6411
Subject: NDA 20-702/S-025 Lipitor	

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES NO

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NDA 20-702/S-025
Lipitor (Atorvastatin)
Parke-Davis (A Warner-Lambert Division)
Submission date: August 10, 2000

Geriatric Labeling Supplement

Within the ACCESS trial please provide answers to the following:

What were the lipid changes at week 6 in ONLY those patients who had received atorvastatin 10 mg?
Please provide the data in a tabular format as follows:

	Non-elderly N=1123	Elderly N=835
mean baseline LDL-C range n		
mean achieved LDL-C range n		
mean % change from baseline (std dev)		

Please provide similar data for total-C, HDL-C, and TGs.

If data on LDL-C changes are not available for all 1,123 non-elderly and 835 elderly subjects, please provide a breakdown summary of reasons why there are missing lipid data (e.g. no baseline lipid data missing, patient inadvertently placed on higher dose of atorvastatin, etc.)

Cleared for faxing by:

Mary Parks, M.D.
Medical Team Leader

**APPEARS THIS WAY
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/s/

Mary Parks

4/6/01 01:21:03 PM

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MEMORANDUM

DATE MAY 25, 2001

TO: Margaret Simoneau
 Project Manager
 HFD-510

FROM: Sue-Jane Wang
 Senior Mathematical Statistician
 HFD-715

THROUGH: Todd Sahlroot
 Team Leader
 HFD-715

RE: NDA#20-702 SE8-025

The ACCESS trial, and the Geriatric Use _____ of the labeling based on the ACCESS trial has been reviewed. As discussed at a recent internal labeling meeting dated May 14, 2001, the statistical review and evaluation of NDA#20-702 SE8-025 will be logged into the DFS system. This document will be used as the review basis should the sponsor submit the ACCESS trial for _____ at a later time. It is noted that the geriatric subpopulation could only be properly evaluated if the original trial population demonstrated a significant atorvastatin effect. Therefore, it is important to have the statistics review completed based on the entire ACCESS trial before evaluation of the geriatric subgroups.

Regarding the sponsor's request for "label based on data submitted to Geriatric Labeling Supplement 025", however, only the portion of the Geriatric Use/Labeling in the Statistical Review and Evaluation would apply.

NDA#20-702 SE8-025
CC: HFD-510/ SIMONEAU, HERMAN, PARKS
 HFD-715/ WANG, SAHLROOT, NEVIUS

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

/s/

Sue Jane Wang
5/31/01 10:35:34 AM
BIOMETRICS

Todd Sahlroot
5/31/01 11:09:32 AM
BIOMETRICS

**APPEARS THIS WAY
ON ORIGINAL**