CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-702/S025

ADMINISTRATIVE DOCUMENTS

[redacted]

Application #(s):	NDA 20-702/S-025
Document Type:	Supplement Letter
Document Group:	Miscellaneous/General Correspondence Letters
Document Name:	
Letter Code:	
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:	
Notes:	
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.

[redacted]

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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 [redacted] This supplement, as amended, proposes the addition of a Geriatric Use subsection.

Please note that a claim regarding [redacted] is considered a separate change from the addition of a Geriatric Use subsection. Therefore, if you wish to pursue the [redacted] we would expect submission of a separate supplement per the Act. In addition, we would expect a user fee for the [redacted] 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

APPEARS THIS WAY
ON ORIGINAL

[redacted]

Application #(s):	NDA 20-702/S-025
Document Type:	NDA IR
COMIS Decision:	
Drafted by:	Mas 4.6.01
Revised by:	
Initialed by:	M. Parks 4.6.01
Finaled:	M. Simoneau (4.6.01)
Filename:	C:\WINDOWS\20702.25IR
DFS Key Words:	
Notes:	Faxed to the sponsor
Linking Instructions:	Link this document to the incoming document the telecon concerns. If there is no such document, then link the document to the initial submission of the IND.

[redacted]

APPEARS THIS WAY
ON ORIGINAL

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

APPEARS THIS WAY
ON ORIGINAL

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
ON ORIGINAL

/s/

Mary Parks
4/6/01 01:21:03 PM

APPEARS THIS WAY
ON ORIGINAL

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