DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-003
NDA 20-702/S-005

JUL 10 1998

Parke-Davis Pharmaceutical Research, agent for
Warner-Lambert Export, Limited
Attention: Byron Scott, R.Ph.
Director Worldwide Regulatory Affairs
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Mr. Scott:

Please refer to your supplemental new drug applications S-003 dated July 16, 1997, received July 17, 1997, and for supplement S-005 dated July 22, 1997, received July 23, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) Tablets, .

We acknowledge receipt of your submissions for Supplement-003 dated August 14, 1997, June 23, 25 (2), 30, and July 8, 1998. The user fee goal date for this application is July 17, 1998. For Supplement-005 we acknowledge receipt of your submissions dated August 14, 1997, April 27, June 2, 15, 23, 25(2), 30, and July 8, 1998. The user fee goal date for this application is July 23, 1998.

The supplemental new drug application S-003 provides for the use of Lipitor (atorvastatin calcium) Tablets as an adjunctive therapy to diet for the treatment of patients with elevated serum triglyceride levels (Frederickson Type IV.)

The supplemental new drug application S-005 provides for the use of Lipitor by patients with primary dysbetalipoproteinemia (Frederickson Type III) who do not respond adequately to diet.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted draft labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on July 8, 1998. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it

is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved NDA 20-702/S-003 and S-005." Approval of these submissions by FDA is not required before the labeling is used.

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,

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