DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-702/S-029, S-034

Pfizer, Inc., Agent for Pfizer Ireland Pharmaceuticals
Attention: John P. Kennedy
Director, Worldwide Regulatory Strategy
235 East 42nd Street 150/7/12
New York, NY 10017

Dear Mr. Kennedy:

Please refer to your supplemental new drug applications, Supplement-029 and Supplement-034, dated August 31 and December 19, 2001, received August 31 and December 20, 2001, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) Tablets.

We acknowledge receipt of your submissions to S-029 dated October 8, 15, 17, and 30, 2001, and March 1 and 21 and April 3 and 12, 2002. We also acknowledge receipt of your submissions to S-034 dated April 3 and 12, 2002. Your April 3, 2002, submission is a complete response to our March 7, 2002, approvable letter for S-034.

Supplement-029 proposes to amend the **DOSAGE AND ADMINISTRATION** section of the Lipitor package insert to add 20 mg and 40 mg daily as optional starting doses with the 40 mg intended for patients who require a large reduction in LDL-C (more than 45%). Supplement–034 provides for replacement of the previous version of the National Cholesterol Education Program (NCEP) Guidelines Table 3 with the updated NCEP Adult Treatment Panel (ATPIII) Guidelines Table 5 and an additional paragraph in the **INDICATIONS AND USAGE** section of the package insert.

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 product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 12, 2002)(copy enclosed).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplement NDA 20-702/S-029, S-034." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, 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

ENCLOSURE

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

/s/

David Orloff

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