



NDA 20-702/S-033

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

Dear Mr. Graham:

Please refer to your supplemental new drug applications dated December 18, 2001, received December 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) Tablets.

We acknowledge receipt of your submissions dated February 12, 13, June 18, September 27 and October 2 and 16, 2002.

This supplemental new drug application provides for the addition of an indication for the treatment of heterozygous familial hypercholesterolemia in adolescent boys and postmenarchal girls, ages 10 to 17 years, with a recommended dosing range of 10 to 20 mg once daily. This supplement responds to our Written Request of February 16, 1999, as amended September 6, 1999 and June 8, 2000.

We have completed the review of this supplemental application, 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, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 16, 2002)(copy enclosed).

Please submit the copies of final printed labeling (FPL) electronically to the application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (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, the submission should be designated "FPL for approved supplement NDA 20-702/S-033." Approval of the submission by FDA is not required before the labeling is used.

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
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/s/

David Orloff
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