



NDA 20-702/S-042

Pfizer Inc., US Agent for
Pfizer Ireland Pharmaceuticals
Attention: Madeleine M. Jester
Director, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Jester:

Please refer to your supplemental new drug application dated December 17, 2004, received December 20, 2004, 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 December 20, and 23, 2004, and February 11, March 16, May 26, September 8, and 13, 2005.

This supplemental new drug application provides for new indications, based on the results of the Collaborative Atorvastatin Diabetes Study (CARDS), for the use of atorvastatin in adult patients with type 2 diabetes and without clinically evident coronary heart disease (but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension), to reduce the risk of myocardial infarction and stroke. In addition, the use of atorvastatin is indicated to reduce the risk of stroke in adult patients without clinically evident coronary heart disease but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease.

In addition, to the Postintroduction Reports, subsection of the **ADVERSE REACTIONS** section of the label, the post-marketing adverse event "fatigue" was added.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted September 13, 2005)(copy enclosed).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-702/S-042.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism and Endocrinology Drug
Products (DMEP)
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/

Mary Parks
9/21/2005 08:15:35 PM
for Dr. Orloff