



NDA 20-702/S-027

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

Dear Ms. Jester:

Please refer to your supplemental new drug application dated June 20, 2001, received June 21, 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 August 17, 2001, November 21, 2003, and May 14, 2004. Your submission of November 21, 2003, constituted a complete response to our August 8, 2002, action letter.

This supplemental new drug application proposes to implement a Patient Package Insert (PPI) for Lipitor.

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 (patient package insert submitted May 14, 2004)(copy enclosed).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-702/S-027." Approval of this submission by FDA is not required before the labeling is used.

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 patient package insert directly to:

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

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, 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks

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