



NDA 20-702/S-043

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 April 11, 2005, received April 12, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (Atorvastatin calcium) tablets.

This supplemental New Drug Application provides for changes to the Lipitor sample labels to which additional promotional messages have been added. The promotional messages consist of statements that say "See other side for more ways to stay on the right track with Lipitor," and "Join the Staying on Track program for tips, rebates and much more! 1.800.843.7567 or stayingontrack.com." This language would appear on the front and back of the 7 count blister pack, the 7 tablet carton, and the display container, and would apply to all strengths: 10, 20, 40, and 80 mg. These are the only packaging elements for Lipitor that would be changed. The Prescribing Information and Patient Package Insert for Lipitor will not be affected.

We completed our review of this application. 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.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. 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-043." 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 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) 796-1295.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.  
Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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Mary Parks  
10/11/2005 01:08:11 PM  
for Dr. Orloff