DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-702/S-036

Pfizer, Inc., Agent for Pfizer Ireland Pharmaceuticals
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 application dated November 26, 2002, received November 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lipitor (atorvastatin calcium) tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to Table 5 in the Lipitor (atorvastatin calcium) package insert.

We completed our review of this supplemental new drug application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 26, 2002.

We also refer to our May 5, 2003, teleconference between you and Dr. Mary Parks of this Division in which you agreed to change the phrase "Lipid-lowering" to "Lipid-altering" in the heading of Table 5. Incorporate this change at the time of the next printing or in your next supplement which contains labeling, whichever occurs first.

The specific change is as follows:

TABLE 5
Lipid-altering Effects of Lipitor in Adolescent Boys and Girls with Heterozygous Familial Hypercholesterolemia or Severe Hypercholesterolemia
(Mean Percent Change from Baseline at Endpoint in Intention-to-Treat Population)

DOSAGE	N	Total-C	LDL-C	HDL-C	TG	Apolipoprotein B
Placebo	47	-1.5	-0.4	-1.9	1.0	0.7
Lipitor	140	-31.4	-39.6	2.8	-12.0	-34.0

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, HF-2
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

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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