



NDA 18422/S-048

APPROVAL LETTER

Pfizer, Inc.
Attention: Kathleen Collins
Manager, Worldwide Regulatory Strategy
235 East 42nd Street (685/18/62)
New York, NY 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application dated January 22, 2009, received January 22, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopid (gemfibrozil) Tablets.

This supplemental new drug application provides for the following revisions to the package insert (PI):

- Removal of the contraindication regarding concomitant use of Lopid with cerivastatin because cerivastatin is no longer a marketed drug product. This revision effects the CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS sections.
- Addition of a contraindication regarding concomitant use of this product with repaglinide due to the risk for severe hypoglycemia. This revisions effects the CONTRAINDICATIONS and PRECAUTIONS sections.
- Removal of the REFERENCES section and all associated cross-references to this section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 22, 2009.

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
Food and Drug Administration
Suite 12B05
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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

Eric Colman
7/14/2009 09:34:12 AM