DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-422/S-043

Pfizer, Inc.
Attention: Marianne Kopelman
Director, Worldwide Regulatory Strategy
235 East 42 Street
New York, NY 10017

Dear Ms. Kopelman:

Please refer to your supplemental new drug applications, S-043, dated October 10, 2002, received October 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopid (gemfibrozil) Tablets.

We also refer to your submission dated January 9, 2003, containing additional copies for the final printed labeling.

The Change Being Effected supplemental new drug application, S-043, provides for revisions to the **WARNINGS,** subsection 2, and **ADVERSE REACTIONS** sections of the Package Insert.

To the **WARNINGS;** subsection 2, the following last sentence has been added:

> "Cases of cholelithiasis have been reported with gemfibrozil therapy (ref. 7)."

To the **ADVERSE REACTIONS** section, the following last sentence has been added:

> "Additional adverse reactions that have been reported include cholecystitis and cholelithiasis (ref. 12) (see WARNINGS)."

We have completed the review of the supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 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

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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