CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-418

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22418 **NDA APPROVAL**

Mutual Pharmaceutical Company, Inc.
Attention: Robert Dettery
VP, Regulatory Affairs
1100 Orthodox Street
Philadelphia, PA 19124

Dear Mr. Dettery:

Please refer to your new drug application (NDA) dated August 15, 2008, received August 15, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fibricor (fenofibric acid) Tablets, 35 mg, 105 mg.

We acknowledge receipt of your submissions dated September 18 and 30, October 10, November 14, December 15, 2008, January 9 and 15, March 4, May 29 and June 3, 2009.

This new drug application provides for the use of Fibricor (fenofibric acid) for the following indications:

- To reduce triglyceride (TG) levels in patients with severe hypertriglyceridemia ($\geq$ 500 mg/dl) .

- To reduce elevated total cholesterol (TC), low-density-lipoprotein cholesterol (LDL-C), TG and apolipoprotein (Apo) B and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia or mixed dyslipidemia.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-418**."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your May 29, 2009, submission containing final printed carton and container labels.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MISCELLANEOUS

Sufficient stability data have been submitted to support a 24-month expiration date.

We note the chemistry, manufacturing, and controls postmarketing agreement that was described in your amendment dated May 29, 2009.

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Container Labels, 35 mg:
30-count bottles
60-count bottles
90-count bottles
100-count bottles
250-count bottles
500-count bottles
1000-count bottles
Container Labels, 105 mg:
30-count bottles
60-count bottles
90-count bottles
100-count bottles
250-count bottles
500-count bottles
1000-count bottles

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC C COLMAN
08/14/2009
Eric Colman for Mary Parks