



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 Fibracor (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 Fibracor (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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ERIC C COLMAN

08/14/2009

Eric Colman for Mary Parks