DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022418/S-008, S-009

SUPPLEMENT APPROVAL

Mutual Pharmaceutical Company, Inc.
Attention: Kim Thorson
Manager, Labeling Compliance
1100 Orthodox Street
Philadelphia, PA 19124

Dear Ms. Thorson:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 8, 2012 (S-008) and November 9, 2012 (S-009), received June 8, 2012 (S-008) and November 9, 2012 (S-009), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FIBRICOR (fenofibric acid) Tablets, 35 mg and 105 mg.

We acknowledge receipt of your e-mail dated December 12, 2012, stating your agreement to the labeling revisions that we communicated to you earlier that day.

Supplement -008, submitted as a "Prior Approval" supplemental new drug application provides for a revised package insert (PI) to include updated information from a repeated drug-drug interaction study. Specifically, Table 3 (Effects of FIBRICOR or Fenofibrate Co-Administration on Systemic Exposure of Other Drugs) has been modified to include information on the effect of FIBRICOR on the AUC and Cmax of Efavirenz. This information had previously been included in the PI, however, you were notified in a September 15, 2011, letter that the FDA had identified violations in bioanalytical studies conducted by Cetero Research (Houston, TX) and you elected to repeat the study using a different facility.

Supplement -009 provides for revisions to the PI in response to our letter dated October 15, 2012, issued to sponsors of marketed fenofibrate products. The primary revisions were made to the following sections:

- Modification of the WARNINGS AND PRECAUTIONS section to include results from the ACCORD Lipid trial;
- Revision of the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections to include information on paradoxical decreases in HDL in patients taking fenofibrates;
- Revisions of the WARNINGS AND PRECAUTIONS and DRUG INTERACTIONS sections to state that cases of myopathy, including rhabdomyolysis, have been reported in patients taking fenofibrates co-administered with colchicine;

Lastly, some additional revisions were made to correct some formatting errors and to further harmonize with other approved fenofibrate products.

We have completed our review of these supplemental applications. They are 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of

promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Amy G. Egan, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AMY G EGAN
12/12/2012