DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022224/S-007, S-008

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Kelly Kaleck-Schlinsog
Associate Director, Regulatory Affairs-PPG
1 N. Waukegan Road
Dept PA77/Building AP30
North Chicago, IL 60064

Dear Ms. Kaleck-Schlinsog:

Please refer to the following Supplemental New Drug Applications (sNDAs) submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trilipix (fenofibric acid) Delayed Release Capsules:

Supplement -007; submitted April 30, 2012, as a "Prior Approval" supplement.

This supplement proposes to add a 30-count aluminum/aluminum blister package as an alternate packaging size for the 45 mg and 135 mg strength capsules. In addition to revisions to the HOW SUPPLIED/STORAGE AND HANDLING section of the package insert, the application contained container (blister) and carton labeling.

Supplement -007; submitted August 15, 2012, as a "Prior Approval" supplement.

Supplement-008 proposed revisions to the package insert in response to our July 6, 2012 letter, requesting the following:

-Revisions to the WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections to include information on paradoxical decreases in HDL-C in patients taking fenofibrates.

-Revisions to 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.

In addition, we requested that the label be revised to further harmonize with other approved fenofibrate products.

We acknowledge receipt of your amendments dated July 18, and August 31, 2012 submitted to Supplement-007. We also acknowledge receipt of your email dated August 31, 2012, stating your agreement to the labeling revisions (package insert) that we communicated to you by email on August 29, 2012.

We have completed our review of these supplemental applications, 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, 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 and Medication Guide), 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

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}

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

ENCLOSURES:
Content of Labeling (Package Insert, Medication Guide)
Carton and Container (Blister) Labeling

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
09/05/2012