DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022224/S-003 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Kelly Kaleck-Schlinsog
Manager, Dyslipidemia
Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road, PA76, AP30-1
Abbott Park, IL 60064-6157

Dear Ms. Kaleck-Schlinsog:

Please refer to your supplemental new drug application dated August 7, 2009, received August 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trilipix (fenofibric acid) Delayed Release Capsules.

We acknowledge receipt of your submissions dated October 13 and 21, 2009, and January 13 and 22, 2010.

This "Prior Approval" supplemental new drug application provides for revisions to the Drug Interactions section of the package insert to delete information that was based on bioanalytical analysis conducted by (b) (4) and replace it with information from other conducted studies. The application also provides for a proposed modification to the approved Risk Evaluation and Mitigation Strategy (REMS), and a REMS assessment.

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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

On January 22, 2010, you submitted a proposed modification and an assessment of your Risk Evaluation and Mitigation Strategy (REMS), originally approved on December 15, 2008. The proposed modified REMS contains a revised Medication Guide which includes Livalo (pitavastatin) Tablets in the list of approved statins, and a timetable for submission of assessments revised to specify the dates the assessments are due and that the assessments will be received by FDA on or before the due dates.

There are no changes to the REMS assessment plan.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(B) and (C), requirements for information on the status of any post-approval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 601.70 and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessment provisions in 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022224 REMS ASSESSMENT
NEW SUPPLEMENT FOR NDA 022224
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022224
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm that is identical to the enclosed agreed-upon labeling text. 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 20-592/S-040/S-041."**

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

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
5600 Fishers Lane, Room 12B05
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).

If you have any questions, call Kati Johnson, 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
- Medication Guide
- REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22224	SUPPL-3	ABBOTT LABORATORIES	TRILIPIX (FENOFIBRIC ACID)

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
09/14/2010