DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22224/S-004

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Kelly Kaleck-Schlinsog
Associate Director, Dyslipidemia & Metabolism
Dept. PA76, Building AP-30-1NE
200 Abbott Park Road
Abbott Park, IL 60064

Dear Ms. Kaleck-Schlinsog:

Please refer to your Supplemental New Drug Application (sNDA) dated February 21, 2011, received February 22, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trilipix (fenofibric acid) Delayed Release Capsules, 45 mg, 135 mg

This "Prior Approval" supplemental new drug application provides for revised bottle and carton labeling to clarify that each capsule contains choline fenofibrate and is equivalent to either 45 mg or 135 mg of fenofibric acid. We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

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

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22224/S-004**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least

24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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:
Carton and Container Labeling:
45 mg, 90-count bottle label
45 mg, 7-count Patient Sample Package
45 mg, sample tray (containing eight 7-count sample packages)
45 mg, Patient Starter Pack (28 capsules)
135 mg, 90-count bottle label
135 mg, 7-count Patient Sample Package
135 mg, sample tray (containing eight 7-count sample packages)
135 mg, Patient Starter Pack (28 capsules)

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
03/14/2011