DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-656/S-004, S-011

Abbott Laboratories
Attention: Natalie Tolli
Associate Director, Dyslipidemia
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Tolli:

Please refer to your supplemental new drug applications dated February 9 (Supplement -004) and November 30, 2006 (Supplement -011), received February 10 and December 4, 2006, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tricor (fenofibrate) Tablets, 48 mg and 145 mg.

We acknowledge receipt of your submissions dated August 3, October 9, 2006, and February 5, 2007 to Supplement -004. Your submission of October 9, 2006 constituted a complete response to our August 10, 2006 action letter for Supplement -004.

These supplemental new drug applications provide for the following revisions to the package insert:
Supplement -004:

-CLINICAL PHARMACOLOGY section, Distribution and Drug-Drug Interactions subsections (to add information on concomitant administration with fluvastatin and ezetimibe). The Special Populations, Renal insufficiency subsection was revised to state that dose reduction is required in patients having mild renal impairment. Previously, the section stated that only moderate impairment required dose adjustment.
-PRECAUTIONS section, Carcinogenesis, Mutagenesis, Impairment of Fertility subsection, as well as the Pregnancy subsection.
-ADVERSE REACTIONS section, to add postmarketing reports
-DOSAGE AND ADMINISTRATION section to revise the dosing in patients with renal impairment.

Supplement -011:

-CLINICAL PHARMACOLOGY section, Drug-Drug Interactions subsection, to add information on concomitant administration with glimepiride, metformin and rosiglitazone.
-ADVERSE REACTIONS section, Cardiovascular System subsection, to add “venous thromboembolic events (deep vein thrombosis, pulmonary embolus)”.

In addition, in a September 5, 2007, telephone conversation, you agreed to accept the inclusion of the following paragraph in the beginning of the “Other Considerations” subsection of the Warnings section. This labeling revision is being requested for all approved fenofibrates.

> "The Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study was a 5-year randomized, placebo-controlled study of 9795 patients with type 2 diabetes mellitus treated with fenofibrate. Fenofibrate demonstrated a non-significant 11% relative reduction in the primary outcome of coronary heart disease events (hazard ratio [HR] 0.89, 95% CI 0.75-1.05, p=0.16) and a significant 11% reduction in the secondary outcome of total cardiovascular disease events (HR 0.89 [0.80-0.99], p=0.04). There was a non-significant 11% (HR 1.11 [0.95, 1.29], p=0.41) and 19% (HR 1.19 [0.90, 1.57], p=0.22) increase in total and coronary heart disease mortality, respectively, with fenofibrate as compared to placebo."

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the 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 submitted, 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 supplemental NDA 19-764/S-037."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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}

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

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

/s/

Eric Colman
9/10/2007 08:50:30 AM
Eric Colman for Mary Parks