DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-304/S-005

APR 2 [illegible] 2000

Abbott Laboratories
Attention: Marilou Reed
Associate Director, Regulatory Affairs
D-491/AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-6108

Dear Ms. Reed:

Please refer to your supplemental new drug application dated June 30, 1999, received July 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tricor (fenofibrate capsules), micronized.

We acknowledge receipt of your submissions dated July 20 and September 16, 1999, and February 21 and 23, March 2, 17, and 24, and April 3, 4, 7, 10, and 11, 2000.

This supplemental new drug application provides for a new indication for the use of Tricor (micronized fenofibrate capsules) to treat patients with Frederickson Type IIa and IIb hyperlipoproteinemia. The labeling will be revised by the addition of a new subsection under the INDICATIONS AND USAGE section of the Tricor package insert entitled, "Treatment of Hypercholesterolemia". Under this subsection, the use of Tricor is indicated as adjunctive therapy to diet for the reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides, and apolipoprotein B (Apo B) in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Frederickson Types IIa and IIb).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 11, 2000).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-304/S-005." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

John R. Jenkins, M.D.
Acting Director
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research