DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-656

Abbott Laboratories
Attention Ernesto J. Rivera, Pharm D.
Regulatory Affairs Manager
200 Abbott Park Road, D-491/AP30-1E
Abbott Park, IL 60064

Dear Dr. Rivera:

Please refer to your new drug application (NDA) dated October 29, 2003, received October 30, 2003, 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 September 9 and 30, and November 4, 2004.

The September 9, 2004, submission constituted a complete response to our August 30, 2004, action letter.

This new drug application provides for the use of Tricor (fenofibrate) Tablets, 48 mg and 145 mg, as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia) and to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb).

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to, the enclosed labeling (text for the package insert, immediate container and carton labels, submitted September 9, 2004). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as stated, in the product‘s labeling may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-656**." Approval of this submission by FDA is not required before the labeling is used.

In addition, you may submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5). Current guidance for industry specifies that the content of labeling should be provided in

PDF or SPL file format. This new submission requirement was published on December 11, 2003, (68 FR 69009) and was effective June 8, 2004. For additional information, consult the following guidance for industry: *Regulatory Submissions in electronic Format—Content of Labeling* (February 2004).

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. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug
Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
Package Insert
Bottle Labels

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

/s/

David Orloff

11/5/04 04:53:20 PM