

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 19-304/S005**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 19-304/S-005

APR 11 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,

/S/

~~John K. 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

APPEARS THIS WAY  
ON ORIGINAL

**CENTER FOR DRUG EVALUATION AND  
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**APPLICATION NUMBER: 19-304/S005**

**APPROVABLE LETTER**

NDA 19-304/S-005

JUL 14 1999

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

Dear Ms. Reed:

We acknowledge receipt of your efficacy supplemental application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tricor™ (fenofibrate capsules), micronized  
NDA Number: 19-304  
Supplement Number: S-005  
Therapeutic Classification: Standard (S)  
Date of Supplement: June 30, 1999  
Date of Receipt: July 01, 1999

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 30, 1999, in accordance with 21 CFR 314.101(a). If the application is filed, the primary user-fee goal date will be May 01, 2000, and the secondary user fee goal date will be July 01, 2000.

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). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within 120 days of receipt of your pediatric drug development plan, we will notify you of the pediatric studies that are required under section 21 CFR 314.55.

If you believe that this drug qualifies for a waiver of the study of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in

accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at [www.fda.gov/cder/pediatric](http://www.fda.gov/cder/pediatric)) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity and will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolic and Endocrine Drug Products, HFD-510  
Attention: Division Document Room, 14B-19  
5600 Fishers Lane  
Rockville, Maryland 20857

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

Sincerely,

*ESJ*

7.14.99

Enid Galliers  
Chief, Project Management Staff  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research