

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

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

**ADMINISTRATIVE DOCUMENTS**

# **NO ADVISORY COMMITTEE MEETING**

**APPEARS THIS WAY  
ON ORIGINAL**

**NO FEDERAL REGISTER NOTICES;  
OTC OR DESI DOCUMENTS**

**APPEARS THIS WAY  
ON ORIGINAL**

**EER**

APPEARS THIS WAY  
ON ORIGINAL

**NOT NEEDED**



— GROUPE —  
**FOURNIER**

DIRECTION GÉNÉRALE

**Exclusivity Certification**

**Investigational Product: Fenofibrate**

I hereby certify that Laboratoires Fournier ("Fournier") has performed a thorough search of the existing literature and to the best of Fournier's knowledge, the literature search is exhaustive and does not provide sufficient basis for the approval of an indication in Type II dyslipidemic patients for the above-cited active moiety.

Furthermore, the studies submitted herein meet the requirements of "new clinical investigations" as defined under 21 CFR 314.108(a). Clinical Study CFEN 8104 was previously submitted to NDA 19-304 however, this study was not used to demonstrate substantial evidence of effectiveness for the approval of the original application in the indication of Type IV/V dyslipidemia.

I also certify that Fournier provided "substantial support" as defined under 21 CFR 314.108(a) for the clinical investigation(s) submitted herein and performed under US IND # \_\_\_\_\_

The rights to the drug have been purchased by Abbott Laboratories, Chicago, IL USA.

**A. Munoz, M.D.**  
**Vice President, Pharmaceutical Division**  
**Groupe Fournier**

EXCLUSIVITY SUMMARY FOR NDA # 19-304

SUPPL # 005

Trade Name TRICOR

Generic Name Fenofibrate Caps. micronized

Applicant Name Abbott

HFD # 510

Approval Date If Known \_\_\_\_\_

**PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?**

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?--  
YES /    / NO / ✓ /

b) Is it an effectiveness supplement?  
YES / ✓ / NO /    /

If yes, what type? (SE1, SE2, etc.) SE1

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES / ✓ / NO /    /

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

\_\_\_\_\_  
\_\_\_\_\_

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

\_\_\_\_\_  
\_\_\_\_\_

d) Did the applicant request exclusivity?

YES /  / NO /  /

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

*3 years*

e) Has pediatric exclusivity been granted for this Active Moiety?

*no*

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /  / NO /  /

If yes, NDA # \_\_\_\_\_ Drug Name \_\_\_\_\_

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /  / NO /  /

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

## PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

### 1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved.

Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

NA

YES /  /      NO /  /

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ON ORIGINAL

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# \_\_\_\_\_  
NDA# \_\_\_\_\_  
NDA# \_\_\_\_\_

2. Combination product. *N/A*

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC Monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /\_\_\_/ NO /\_\_\_/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# \_\_\_\_\_  
NDA# \_\_\_\_\_  
NDA# \_\_\_\_\_

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

**PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS**

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /  / NO /  /

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /  / NO /  /

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

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(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /  / NO /  /

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /  / NO /  /

If yes, explain: \_\_\_\_\_  
\_\_\_\_\_

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /  / NO /  / *NA*

If yes, explain: \_\_\_\_\_  
\_\_\_\_\_

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

CFEN 8104, 8502, 8802, 9116

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.



4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1  
 IND #        YES /  / NO /    / Explain:                   

Investigation #2, #3, #4  
 IND #        YES /  / NO /    / Explain:                   

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1  
 YES /    / Explain            NO /    / Explain           

Investigation #2  
 YES /    / Explain            NO /    / Explain

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /  /

NO /  /

If yes, explain: \_\_\_\_\_  
\_\_\_\_\_

ISI  
Signature \_\_\_\_\_  
Title: Project Manager

4-6-00  
Date \_\_\_\_\_

ISI  
Signature of Office /  
Division Director \_\_\_\_\_

4/21/00  
Date \_\_\_\_\_

cc: Original NDA

Division File

HFD-85 Mary Ann Holovac

APPEARS THIS WAY  
ON ORIGINAL

# PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

**E:** A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

NDA/BLA # 19-304 Supplement # 005 Circle one  SE1 SE2 SE3 SE4 SE5 SE6

HEB-510 Trade and generic names/dosage form: Tricor (fenofibrate capsules) <sup>micronized</sup> Action:  AP AE NA

Applicant Abbott Therapeutic Class Lipid ALTERING AGENTS  
Treatment of Adults (Types 4 & 5 hyperlipidemia) at risk of pancreatitis

Indication(s) previously approved \_\_\_\_\_

Pediatric information in labeling of approved indication(s) is adequate  inadequate

Proposed indication in this application Addition of a new subsection under the Indications + Usage section entitled

"Treatment of Hypercholesterolemia": reduction of LDL-C, Total C, TG, and Apo B in adults - Primary or mixed dyslipidemia

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.

IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS?  Yes (Continue with questions)  No (Sign and return the form) (FRED UAT II b)

WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)

Neonates (Birth-1month)  Infants (1month-2yrs)  Children (2-12yrs)  Adolescents(12-16yrs)

1. PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS. Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.

2. PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS. Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

3. PEDIATRIC STUDIES ARE NEEDED. There is potential for use in children, and further information is required to permit adequate labeling for this use.

a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.

b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.

c. The applicant has committed to doing such studies as will be required.

- (1) Studies are ongoing.
- (2) Protocols were submitted and approved.
- (3) Protocols were submitted and are under review.
- (4) If no protocol has been submitted, attach memo describing status of discussions.

d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

4. PEDIATRIC STUDIES ARE NOT NEEDED. The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

5. If none of the above apply, attach an explanation, as necessary.

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER?  Yes  No  
ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from Med. Trm. Ldr (e.g., medical review, medical officer, team leader)

IS/  
Signature of Preparer and Title

4-7-00  
Date

Orig NDA/BLA # 19-304  
HFD 510 Div File  
NDA/BLA Action Package  
HFD-006/ KRoberts

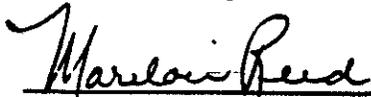
(revised 10/20/97)

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT, KHYATI ROBERTS, HFD-6 (ROBERTSK)

**DEBARMENT STATEMENT**

In compliance with the generic Drug Enforcement of 1992, Section 306(k)(1) of the act (21 USC 355a(k)(1)), we, Abbott Laboratories, certify the following with respect to this Supplemental New Drug Application:

The applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) (sections 306(a) or (b) of the Federal, Food, Drug, and Cosmetic Act), in connection with this supplemental application for approval of a new indication of a drug product.



Marjou Reed, Associate Director  
PPD Regulatory Affairs  
D-491, AP6B/1  
Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, Illinois 60064-3500

6/30/99  
Date

APPEARS THIS WAY  
ON ORIGINAL

# CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

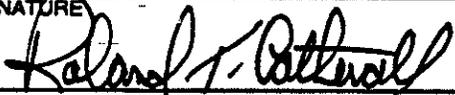
Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Roland T. Catherall	TITLE Vice President, Regulatory Affairs and Research Quality Assurance
FIRM/ORGANIZATION Abbott Laboratories/Pharmaceutical Products Division	
SIGNATURE 	DATE 6/29/99

### Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14C-03  
Rockville, MD 20857



— GROUPE —  
**FOURNIER**

DIRECTION GÉNÉRALE **Financial Disclosure Certification**

**Investigational Product: Fenofibrate**

With respect to the clinical studies C FEN 8104, C FEN 8502, C FEN 8802, C FEN 9116 for the above referenced product that were conducted for Laboratoires Fournier ("Fournier"), I hereby certify to the truth and accuracy of the following statements in compliance with 21 CFR part 54 with the understanding that I am certifying on behalf of all clinical investigators, and also for their respective spouses and dependent children, who conducted clinical investigations referenced herein.

I certify that no investigator, has entered into any financial arrangement with Fournier (e.g., bonus, royalty or other financial incentive) whereby the outcome of the clinical study they participated in could affect their compensation.

In addition, I certify that no investigator has any proprietary interest (e.g., patent, trademark, copyright, licensing agreement, etc.) in the product tested in the clinical study.

A. Munoz  
Vice President, Pharmaceutical Division

APPEARS THIS WAY  
ON ORIGINAL

**DSI**

**NOT NEEDED**