

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-224

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

Department of Health and Human Services Food and Drug Administration		Form Approved: OMB No. 0910-0913 Expiration Date: 07/31/08 See OMB Statement on Page 3.	
PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT <i>For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use</i>		NDA NUMBER	
		NAME OF APPLICANT / NDA HOLDER Abbott Laboratories	
<i>The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.</i>			
TRADE NAME (OR PROPOSED TRADE NAME) Not yet determined			
ACTIVE INGREDIENT(S) Choline Fenofibrate		STRENGTH(S) 45mg and 135 mg	
DOSAGE FORM Tablets			
This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4). Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book.			
For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.			
FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.			
For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.			
1. GENERAL			
a. United States Patent Number 7,259,186		b. Issue Date of Patent 8/21/2007	c. Expiration Date of Patent 7/23/2025
d. Name of Patent Owner Abbott Laboratories		Address (of Patent Owner) D 0377/B-AP6A-1, 100 Abbott Park Rd.	
		City/State Abbott Park, IL	
		ZIP Code 60064	FAX Number (if available) 847-938-2623
		Telephone Number 847-937-6364	E-Mail Address (if available)
e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States) ☐		Address (of agent or representative named in 1.e.)	
		City/State	
		ZIP Code	FAX Number (if available)
		Telephone Number	E-Mail Address (if available)
f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 			
g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? <input type="checkbox"/> Yes <input type="checkbox"/> No 			

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? Yes No

2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? Yes No

2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b). Yes No

2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.

2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.) Yes No

2.6 Does the patent claim only an intermediate? Yes No

2.7 If the patent referenced in 2.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement? Yes No

3.2 Does the patent claim only an intermediate? Yes No

3.3 If the patent referenced in 3.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No

4.2 Patent Claim Number (as listed in the patent) Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No

4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product. *Use: (Submit indication or method of use information as identified specifically in the approved labeling.)*

5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Yes

6. Declaration Certification	
<p>6.1 <i>The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 805 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.</i></p> <p><i>Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.</i></p>	
<p>6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide information below)</p> <p>X </p>	<p>Date Signed 10/16/2007</p>
<p>NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).</p>	
<p>Check applicable box and provide information below.</p>	
<input checked="" type="checkbox"/> NDA Applicant/Holder	<input type="checkbox"/> NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
<input type="checkbox"/> Patent Owner	<input type="checkbox"/> Patent Owner's Attorney, Agent (Representative) or Other Authorized Official
<p>Name Robert DeBerardine</p>	
<p>Address D-0377/B-AP6A-1, 100 Abbott Park Rd.,</p>	<p>City/State Abbott Park, IL</p>
<p>ZIP Code 60064</p>	<p>Telephone Number 847-937-6364</p>
<p>FAX Number (if available) 847-938-2623</p>	<p>E-Mail Address (if available)</p>
<p>The public reporting burden for this collection of information has been estimated to average 9 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Food and Drug Administration CDER (HFD-007) 5600 Fishers Lane Rockville, MD 20857</p> <p style="text-align: center;"><i>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.</i></p>	

INFORMATION AND INSTRUCTIONS FOR FORM 3542a
PATENT INFORMATION SUBMITTED WITH THE FILING
OF AN NDA, AMENDMENT OR SUPPLEMENT

General Information

- To submit patent information to the agency the appropriate patent declaration form must be used. Two forms are available for patent submissions. The approval status of your New Drug Application will determine which form you should use.
- Form 3542a should be used when submitting patent information with original NDA submissions, NDA amendments and NDA supplements prior to approval.
- Form 3542 should be used after NDA or supplemental approval. This form is to be submitted within 30 days after approval of an application. This form should also be used to submit patent information relating to an approved supplement under 21 CFR 314.53(d) to change the formulation, add a new indication or other condition of use, change the strength, or to make any other patented change regarding the drug, drug product, or any method of use.
- Form 3542 is also to be used for patents issued after drug approval. Patents issued after drug approval are required to be submitted within 30 days of patent issuance for the patent to be considered "timely filed."
- Only information from form 3542 will be used for Orange Book Publication purposes.
- Forms should be submitted as described in 21 CFR 314.53. An additional copy of form 3542 to the Orange Book Staff will expedite patent publication in the Orange Book. The Orange Book Staff address (as of July 2003) is: Orange Book Staff, Office of Generic Drugs OGD/HFD-610, 7500 Standish Place, Rockville, MD 20855.
- The receipt date is the date that the patent information is date stamped in the central document room. Patents are considered listed on the date received.
- Additional copies of these forms may be downloaded from the Internet at: <http://forms.fda.gov/forms/3542a/3542a.htm>.

First Section

Complete all items in this section.

1. General Section

Complete all items in this section with reference to the patent itself.

- 1c) Include patent expiration date, including any Hatch-Waxman patent extension already granted. Do not include any applicable pediatric exclusivity. The agency will include pediatric exclusivities where applicable upon publication.
- 1d) Include full address of patent owner. If patent owner resides outside the U.S. indicate the country in the zip code block.

- 1e) Answer this question if applicable. If patent owner and NDA applicant/holder reside in the United States, leave space blank.

2. Drug Substance (Active Ingredient)

Complete all items in this section if the patent claims the drug substance that is the subject of the pending NDA, amendment, or supplement.

- 2.4) Name the polymorphic form of the drug identified by the patent.
- 2.5) A patent for a metabolite of the approved active ingredient may not be submitted. If the patent claims an approved method of using the approved drug product to administer the metabolite, the patent may be submitted as a method of use patent depending on the responses to section 4 of this form.
- 2.7) Answer this question only if the patent is a product-by-process patent.

3. Drug Product (Composition/Formulation)

Complete all items in this section if the patent claims the drug product that is the subject of the pending NDA, amendment, or supplement.

- 3.3) An answer to this question is required only if the referenced patent is a product-by-process patent.

4. Method of Use

Complete all items in this section if the patent claims a method of use of the drug product that is the subject of the pending NDA, amendment, or supplement.

- 4.2) Identify by number each claim in the patent that claims the use(s) of the drug for which approval is being sought. Indicate whether or not each individual claim is a claim for a method(s) of use of the drug for which approval is being sought.
- 4.2a) Specify the part of the proposed drug labeling that is claimed by the patent.

5. No Relevant Patents

Complete this section only if applicable.

6. Declaration Certification

Complete all items in this section.

- 6.2) Authorized signature. Check one of the four boxes that best describes the authorized signature.

4/10/08



TriLipix™ (Fenofibric acid) Delayed-Release Capsules
NDA 022224
1.3.5.2 Patent Certification

1.3.5.2 Patent Certification (Form FDA 356h Item 14)

As required by 21 CFR 314.50 (i)(1)(i) and (ii), the following patent certification is hereby provided for our New Drug Application 022224 for TriLipix™ delayed-release capsules.

Reference Listed Drug – Simvastatin (Zocor®) – Patent has expired – Paragraph II Certification

The undersigned declares that to the best of our knowledge, there are no patents that are relevant to the investigations, or use of simvastatin, relied upon in this application.

Signed: Natalie Tolli
 Associate Director, Dyslipidemia
 Global Pharmaceutical Regulatory Affairs
 Abbott Laboratories

EXCLUSIVITY SUMMARY

NDA # 22-224

SUPPL #

HFD # 510

Trade Name Trilipix Delayed Release Capsules

Generic Name fenofibric acid

Applicant Name Abbott

Approval Date, If Known 12/15/08

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

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

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES

NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

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?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

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

YES NO

IF THE ANSWER TO QUESTION 2 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.

YES NO

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

NDA# 21-656 Tricor
NDA# 21-350 Triglide
NDA# 22-118 Xyglide

2. Combination product.

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. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)

IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs 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:

(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

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:

Study 748: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Rosuvastatin Calcium Combination Therapy to Fenofibric Acid and Rosuvastatin Calcium Monotherapy in Subjects With Mixed Dyslipidemia

Study 749: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Simvastatin Combination Therapy to Fenofibric Acid and Simvastatin Monotherapy in Subjects With Mixed Dyslipidemia

Study 750: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Atorvastatin Calcium Combination Therapy to Fenofibric Acid and Atorvastatin Calcium Monotherapy in Subjects With Mixed Dyslipidemia

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.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Study 748: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Rosuvastatin Calcium Combination Therapy to Fenofibric Acid and Rosuvastatin Calcium Monotherapy in Subjects With Mixed Dyslipidemia

Study 749: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Simvastatin Combination Therapy to Fenofibric Acid and Simvastatin Monotherapy in Subjects With Mixed Dyslipidemia

Study 750: A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and

**Efficacy of Fenofibric Acid and Atorvastatin Calcium
Combination Therapy to Fenofibric Acid and
Atorvastatin Calcium Monotherapy in Subjects With
Mixed Dyslipidemia**

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 !
!
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 ! NO
Explain: ! 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:

Name of person completing form: Kati Johnson

Title: Project Manager

Date: 12/17/08

Name of Office/Division Director signing form: Eric Colman

Title: Deputy Division Director/Lipid Team Leader

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

Appears This Way
On Original

**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

12/17/2008 08:58:58 AM

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On Original



ABT-335 (Choline Fenofibrate Oral Capsules)
NDA 22-224
Debarment Certification

Debarment Certification

Certification Requirement for Approval of a Drug Product Concerning Using Services of Debarred Persons

Any applicant for approval of a new drug product submitted on or after June 1, 1992 per Section 306(k)(1) of the Federal Food, Drug, and Cosmetic Act must include:

- (1) A certification that the applicant did not and will not use in any capacity the services of any person debarred under Section 306, subsection (a) and (b), in connection with such application.

Abbott Laboratories certifies that it did not, and will not use in any capacity the services of any person debarred under Section 306, subsection (a) and (b), in connection with this application.

Natalie Tolli
Associate Director
Global Pharmaceutical Regulatory Affairs
Abbott Laboratories

Appears This Way
On Original



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

11/4/08

NDA 22-224

Abbott Laboratories
Attention: Natalie Tolli
Associate Director, Dyslipidemia
200 Abbott Park Road
Dept. PA76, Bldg. AP30-1NE
Abbott Park, IL 60064-6157

Dear Ms. Tolli:

Please refer to your December 7, 2007 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trilipix (fenofibric acid) Delayed Release Capsules.

We acknowledge receipt of your submissions dated March 20, April 7 and 10, May 7, June 6, 9, 13 and 23, August 7, 21 and 25, September 9 and 30 (2 submissions), October 2 (2 submissions), 8 and 15, 2008.

We are reviewing your submissions and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your application.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Title IX, Subtitle A, Section 901 of Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the FDCA to authorize FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)). This provision took effect on March 25, 2008.

In accordance with section 505-1 of FDCA, we have determined that a REMS is necessary for Trilipix (fenofibric acid) to ensure that the benefits of the drug outweigh the risk of rhabdomyolysis when Trilipix is co-administered with a statin. Approved statin and fibrate package inserts include warnings against the co-administration of a fibrate and a statin due to the increased occurrence of rhabdomyolysis. In contrast to other fibrates none of which are approved for co-administration with a statin, Trilipix (fenofibric acid) is indicated for co-administration with a statin.

Your proposed REMS must contain the following:

Medication Guide: As one element of a REMS, FDA may require the development of a Medication Guide as provided for under 21 CFR Part 208. Pursuant to 21 CFR Part 208, FDA has determined that Trilipix (fenofibric acid) poses a serious and significant public health concern requiring the distribution of a Medication Guide. The Medication Guide is necessary for patients' safe and effective use of Trilipix (fenofibric acid). FDA has determined that Trilipix (fenofibric acid) is a product that has a serious risk (relative to benefits) of which patients should be made aware because information concerning the risk could affect patients' decisions to use, or continue to use Trilipix (fenofibric acid). Under 21 CFR Part 208 and in accordance with 505-1, you are responsible for ensuring that the Medication Guide is available for distribution to patients who are dispensed Trilipix (fenofibric acid).

Timetable for Assessment: The proposed REMS must include a timetable for assessment of the REMS that shall be no less frequent than by 18 months, by 3 years, and in the 7th year after the REMS is approved. We recommend that you specify the interval that each assessment will cover and the planned date of submission to the FDA of the assessment. We recommend that assessments be submitted within 60 days of the close of the interval.

Your REMS assessments must assess the extent to which the elements of your REMS are meeting the goals of your REMS and whether modifications to the elements or goals are needed.

In accordance with section 505-1, you must submit a proposed REMS. Before we can continue our evaluation of NDA 22-224, you will need to submit the proposed Trilipix (fenofibric acid) REMS to this application. The REMS, once approved, will create enforceable obligations.

We suggest that your proposed REMS submission include two parts: a "Proposed REMS" and a "REMS Supporting Document." Attached is a template for the Proposed REMS that you should complete with concise, specific information (see Appendix A). Include information in the template that is specific to your proposed REMS for Trilipix (fenofibric acid). Additionally, the Medication Guide should be appended to the proposed REMS. Once FDA finds the content acceptable, we will include this document as an attachment to the approval letter that includes the REMS.

The REMS Supporting Document should be a document explaining the rationale for each of the elements included in the proposed REMS (see Appendix B).

Your assessment of the REMS should include an evaluation of:

- a. Patients' understanding of the serious risks of Trilipix (fenofibric acid)
- b. A report on periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24.
- c. A report on failures to adhere to distribution and dispensing requirements, and corrective actions taken to address noncompliance.

If you do not submit electronically, please send 5 copies of your proposed REMS as an amendment to your NDA. Prominently identify the amendment containing the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

PROPOSED REMS FOR NDA 22-224

Prominently identify subsequent submissions related to the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

**NDA 22-224
PROPOSED REMS – AMENDMENT**

If you have any questions, please call Kati Johnson, Regulatory Health Project Manager, at (301)796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Appendix A – REMS Template
Appendix B – REMS Supporting Document Template

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Appendix A – REMS TEMPLATE

NDA 22-224 TRILIPIX (FENOFIBRIC ACID) DELAYED RELEASE CAPSULES

Peroxisome proliferator receptor alpha (PPAR α) activator

**Abbott Laboratories
200 Abbott Park Road
Dept. PA76, Bldg. AP30-1NE
Abbott Park, Il 60064-6157**

**Natalie Tolli
Associate Director, Dyslipidemia
(P) 847-935-8099
(F) 847-775-4982
Natalie.Tolli@abbott.com**

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

List the goals and objectives of the REMS

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each Trilipix (fenofibric acid) prescription.
[Describe in detail how you will comply with 21 CFR 208.24.]

B. Communication Plan

This REMS for Trilipix (fenofibric acid) can be approved without a communication plan.

C. Elements To Assure Safe Use

This REMS for Trilipix (fenofibric acid) can be approved without any elements to assure safe use.

D. Implementation System

Because this REMS for Trilipix (fenofibric acid) can be approved without any elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

Specify the timetable for submission of assessments of the REMS. The timetable for submission of assessments at a minimum must include an assessment by 18 months, 3 years, and in the 7th year after the REMS is initially approved, with dates for additional assessments if more frequent assessments are necessary to ensure that the benefits of the drug continue to outweigh the risks.

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Appendix B - REMS Supporting Document Template

This REMS Supporting Document should include the following listed sections 1 through 5, as well as a table of contents. If you are not proposing to include one of the listed elements, the REMS Supporting Document should simply state that the element is not necessary. Include in section 3 the reason you believe each of the potential elements you are proposing to include in the REMS is necessary to ensure that the benefits of the drug outweigh the risks.

1. Background
2. Goals
3. Supporting Information on Proposed REMS Elements
 - a. Additional Potential Elements
 - i. Medication Guide
 - ii. Patient Package Insert
 - iii. Communication Plan
 - b. Elements to Assure Safe Use, including a statement of how the elements to assure safe use will mitigate the observed safety risk
 - c. Implementation System
 - d. Timetable for Assessment of the REMS
4. Information Needed for Assessments
5. Other Relevant Information

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/s/

Eric Colman
11/4/2008 05:57:47 PM
Eric Colman for Mary Parks

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Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6188

PMCL

Date of Submission: October 15, 2008

**Dr. Mary Parks
Division Director
Division of Metabolic and Endocrinology Products
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266**

AMENDMENT TO A PENDING APPLICATION

**Re: Trilipix™ (Fenofibric acid) Delayed Release Capsules
NDA 022224, eCTD Sequence 0018**

**Subject: Response to an Agency Request for Study Milestone Dates, for a PK Dose
Equivalence Study**

Dear Dr. Parks:

The sponsor, Abbott Laboratories, submits under the provisions of Section 505 (b) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50, a New Drug Application for Trilipix™ (fenofibric acid) (NDA 022224), which was originally submitted on December 7, 2007.

The purpose of this submission is to provide milestone dates for a post-approval pharmacokinetic (PK) study that has been requested by the Agency. Specifically, the Agency has requested that Abbott perform a dose equivalency study of Trilipix, to compare the PK of 3 x 45 mg Trilipix capsules against 1 x 135 mg Trilipix capsule.

Abbott



Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6188

Abbott is proposing the following milestone dates for the above study:

- Final protocol submission: _____
- Study start: _____
- Submission of final CSR: _____

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Abbott is available if the Agency feels a discuss is needed for these proposed dates.

This submission is being provided electronically. It was created in accordance with *FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specification, effective June 2008, Revision 2*. The approximate size of the application is less than 5 megabytes and will be transmitted via the FDA Gateway. The content of the submission was checked for viruses using McAfee VirusScan 8.0i and was determined to be virus free.

Please note the new fax number noted below. Please discontinue use of previous fax numbers associated with this application. For all future faxed communication concerning this application, please use the (847) 775 4982 number.

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Abbott



Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6188

Should you have any questions concerning this submission, please contact us at the numbers provided below. Thank you for your consideration in this matter.

Sincerely,

ABBOTT LABORATORIES

Regulatory Point of Contact

Natalie Tolli
Director, Global Pharmaceutical Regulatory Affairs
E-mail: Natalie.Tolli@Abbott.com
TEL: (847) 935 8099
FAX: (847) 775 4942

Technical Point of Contact

Tina Lewis
Director, Global Pharmaceutical Regulatory Affairs
E-mail: Tina.M.Lewis@Abbott.com
TEL: (847) 936-8944
FAX: (847) 936-6778

Confidential Information

This application contains trade secret and/or confidential information, which is the property of Abbott Laboratories. As provided by 21 CFR 20.61, DO NOT DISCLOSE to the public.

Abbott

Johnson, Kati

From: Duvall Miller, Beth A
Sent: Monday, October 06, 2008 5:19 PM
To: Johnson, Kati
Cc: Colangelo, Kim M
Subject: NDA 22-224, Fenofibrate - cleared for action

Kati,

This application is cleared for action from a b(2) perspective. Thanks,

Beth

Beth Duvall-Miller
Team Leader, Regulatory Affairs Team
CDER/Office of New Drugs
Direct Phone Number: (301) 796-0513
OND IO Phone Number: (301) 796-0700
Fax: (301) 796-9858

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9/17/08

MEMORANDUM

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

CLINICAL INSPECTION SUMMARY

DATE: September 15, 2008

TO: Kati Johnson, Regulatory Project Manager
Julie Golden, MD, Medical Officer
Eric Coleman MD, Lipid Team Leader
Division of Metabolic and Endocrinology Products

FROM: Susan Leibenhaut, MD
Good Clinical Practice Branch I
Division of Scientific Investigations

THROUGH: Constance Lewin, MD, MPH
Branch Chief
Good Clinical Practice Branch I
Division of Scientific Investigations

SUBJECT: Evaluation of Clinical Inspections.

NDA : NDA 22-224

APPLICANT: Abbott Labs

DRUG: Trilipix (fenofibrate) Capsules 45 mg, 135 mg

NME: No

THERAPEUTIC CLASSIFICATION: Standard Review

INDICATIONS: Treatment of dyslipidemia (mixed dyslipidemia [in combination with HMG-CoA reductase inhibitors (statins), or as monotherapy], primary hypercholesterolemia [as monotherapy], or hypertriglyceridemia [as monotherapy])

CONSULTATION REQUEST DATE: 3/3/08

DIVISION ACTION GOAL DATE: 10/7/08

PDUFA DATE: 10/7/08

I. BACKGROUND:

NDA 22-224 is a 505(b)(2) application for fenofibrate, an ester that is converted to the active circulating form of fenofibric acid. The Phase 3 program included three similar Phase 3 studies to evaluate the safety and efficacy of ABT-335 co-administered with 3 different statins, one for each study.

The goals of the inspection were to assess adherence to FDA regulatory requirements concerning investigator oversight, protocol compliance, validity of primary efficacy endpoint data, and protection of subjects' rights, safety, and welfare. The number of subjects randomized and proportion discontinued in a particular site was taken into account in selecting sites for auditing.

The protocols inspected were:

- A. Protocol MO5-748 entitled "A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Rosuvastatin Calcium Combination Therapy to Fenofibric Acid and Rosuvastatin Calcium Monotherapy in Subjects With Mixed Dyslipidemia"
- B. Protocol MO5-749 entitled "A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Simvastatin Combination Therapy to Fenofibric Acid and Simvastatin Monotherapy in Subjects With Mixed Dyslipidemia"
- C. Protocol MO5-750 entitled "A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Atorvastatin Calcium Combination Therapy to Fenofibric Acid and Atorvastatin Calcium Monotherapy in Subjects With Mixed Dyslipidemia"

II. RESULTS (by Site):

Name of CI and CRO Location	Protocol # and # of Subjects:	Inspection Date	Final Classification
CI: Neil J. Fraser, MD Troy Internal Medicine Research 4550 Investment Drive, Suite 210 Troy, MI	Protocol 748/ Site # 31810/ 29 randomized	April 21-25, 2008	NAI
CI: Cecil Farrington, Jr, MD Crescent Medical Research Assoc. 401 Mocksville Ave, Suite 300 Salisbury, NC 28144	Protocol 748/ Site # 32430/ 20 randomized	June 9-11, 2008	NAI
CI: Angel O. Pietri, MD 12631 World Plaza Lane Building #54 Ft. Myers, Florida 33907	Protocol 749/ Site # 24076/ 16 randomized	June 2-6, 2008	VAI

CI: Timothy J. Jones, MD 1483 Tobias Gadson Blvd. Suite 101 Charleston, SC 29407	Protocol 749/ Site # 31018/ 16 randomized	April 28-29, 2008	NAI
CI: Michael J. Koren, MD Jacksonville Center for Clinical 4085 University Blvd. S, Suite 1 Jacksonville, FL 32216	Protocol 750/ Site # 16155/ 31 randomized	May 22, 2008	NAI
CI: Gregory M. Gottschlich, MD New Horizon Clinical Research 4260 Glendale Milford Road Suite 201 Cincinnati, OH 45242	Protocol 750/ Site # 9337/ 23 randomized	May 19-28, 2008	Pending (Preliminary classification NAI)
CRO L	Protocols 748, 749, 750	April 23-May 12, 2008	NAI

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Key to Classifications

NAI = No deviation from regulations.

VAI = Deviation(s) from regulations.

OAI = Significant deviations from regulations.

Pending = Preliminary classification based on information in 483 or preliminary communication with the field;
EIR has not been received from the field and complete review of EIR is pending.

1. Neil J. Fraser, MD
Troy Internal Medicine Research
4550 Investment Drive, Suite 210
Troy, MI
 - a. **What was inspected:** This site participated in Protocol 748 as Site #31810. The investigator screened 64 potential subjects and randomized 29 subjects. Consent forms, case report forms and source documents were reviewed for all 29 subjects. There were no limitations to the inspection.
 - b. **General observations/commentary:** No significant regulatory violations were noted.
 - c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.

2. Cecil Farrington, Jr, MD
Crescent Medical Research Assoc.
401 Mocksville Ave, Suite 300
Salisbury, NC 28144
- a. **What was inspected:** This site participated in Protocol 748 as Site # 32430. The investigator screened 70 potential subjects and randomized 20 subjects. Consent forms, case report forms and source documents were reviewed for all 20 subjects. There were no limitations to the inspection.
 - b. **General observations/commentary:** No significant regulatory violations were noted.
 - c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.
3. Angel O. Pietri, MD
12631 World Plaza Lane Building #54
Ft. Myers, Florida 33907
- a. **What was inspected:** This site participated in Protocol 749 as Site # 24076. The investigator screened 48 potential subjects and randomized 16 subjects. Consent forms were reviewed for all subjects. Case report forms and source documents and data listings were reviewed for 9 of 16 randomized subjects. Baseline laboratory values were audited for 11 of the 16 randomized subjects. There were no limitations to the inspection.
 - b. **General observations/commentary:** The clinical investigator did not maintain adequate and accurate case histories with respect to observations and data pertinent to the investigation. Following are some examples:
 - The subject visit sign in form indicates that Subject #601229/21028 Visit 3-Baseline visit occurred on 8/17/2006. However, the laboratory reports and IVRS Randomization Notification indicate that the subject was present for the Visit 3-Baseline visit on 8/16/2006.
 - Source document concomitant medication log for Subject 600469/22014 records that Motrin 200mg was taken BID on June 30 and July 2, 2006 and once on July 12, 2006. However, the case report form (CRF) states that two tabs Motrin 200mg (total 400mg) was taken at these times.
 - Source document concomitant medication log for Subject 600263/21006 records that Glucovance 5/500mg is taken BID for diabetes maintenance. However, the case report form (CRF) states that Glucovance 50/500mg is taken BID for diabetes maintenance.

- c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.

4. Timothy J. Jones, MD
1483 Tobias Gadson Blvd. Suite 101
Charleston, SC 29407

- a. **What was inspected:** This site participated in Protocol 749 as Site # 31018. The investigator screened 68 potential subjects, enrolled and randomized 16 subjects. Consent forms, case report forms and source documents were reviewed for all subjects. There were no limitations to the inspection.
- b. **General observations/commentary:** No significant regulatory violations were noted.
- c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.

5. Michael J. Koren, MD
Jacksonville Center for Clinical Research
4085 University Blvd. S, Suite 1
Jacksonville, FL 32216

- a. **What was inspected:** This site participated in Protocol 750 as Site #16155. The investigator screened 82 potential subjects, enrolled and randomized 31 subjects. Consent forms and endpoint data verification were reviewed for all enrolled subjects. There were no limitations to the inspection.
- b. **General observations/commentary:** No significant regulatory violations were noted.
- c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.

6. Gregory M. Gottschlich, MD
New Horizon Clinical Research
4260 Glendale Milford Road, Suite 201
Cincinnati, OH 45242

- a. **What was inspected:** This site participated in Protocol 750 as Site #9337. The investigator enrolled 23 subjects; 2 subjects discontinued early and 21 completed the study. A 100% review of the 23 subjects was conducted and no deviations were noted. There were no limitations to the inspection.
- b. **General observations/commentary:** No significant regulatory violations were noted.
- c. **Data acceptability/reliability:** Data from this site appear acceptable in support of the application.

Observations noted above for this site are based on the Form FDA 483 and communications with the field investigator, an inspection summary addendum will be generated if conclusions change upon receipt and review of the Establishment Inspection Report (EIR).

7.

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- a. **What was inspected:** The CRO was inspected because the primary efficacy endpoint data was stored at this site and was not available at the clinical sites. The source data was reviewed for approximately 700 data points of triglyceride, HDL and LDL of subjects in the three protocols. There were no limitations to the inspection.
- b. **General observations/commentary:** No significant regulatory violations were noted.
- c. **Data acceptability/reliability:** Laboratory data from this contract research organization appear acceptable in support of the application.

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IV. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

The inspection of Dr. Pietri found regulatory violations as noted above. All other inspections did not find violations. The data from all sites and from the contract laboratory appear acceptable in support of the respective indications.

The final classification for Dr. Gottschlich is pending. An addendum to this clinical inspection summary will be forwarded to the review division should there be a change in the final classification or additional observations of clinical and regulatory significance are discovered after reviewing the EIR.

{See appended electronic signature page}

Susan Leibenhaut, M.D
Good Clinical Practice Branch I
Division of Scientific Investigations

CONCURRENCE:

{See appended electronic signature page}

Constance Lewin, MD, MPH
Branch Chief
Good Clinical Practice Branch I
Division of Scientific Investigations

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/s/

Susan Leibenhaut
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MEDICAL OFFICER

Constance Lewin
9/17/2008 12:58:47 PM
MEDICAL OFFICER

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9/12/08

MEMORANDUM

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

DATE: September 12, 2008

TO: Mary H. Parks, M.D.
Director, Division of Metabolism and Endocrinology
Products (DMEP)

FROM: Jacqueline A. O'Shaughnessy, Ph.D.
Abhijit Raha, Ph.D.
Division of Scientific Investigations (HFD-48)

THROUGH: C.T. Viswanathan, Ph.D.
Associate Director - Bioequivalence
Division of Scientific Investigations (HFD-48)

SUBJECT: Review of EIRs Covering NDA 22-224, Choline
Fenofibrate Oral Capsules, 45 mg and 135 mg, Sponsored
by Abbott Laboratories

At the request of Division of Metabolism and Endocrinology Products, the Division of Scientific Investigations audited the clinical and analytical portions of the following bioequivalence study:

Study Number: M06-830

Study Title: "Evaluation of the Relative Bioavailability of Fenofibric Acid from Fenofibric Acid Choline Salt Formulations Manufactured at Two Different Sites and Batch Sizes, and 200 mg Micronized Fenofibrate Capsule"

The clinical and analytical portions of Study M06-830 were conducted at Abbott Clinical Pharmacology Research Unit at Vista Medical Center (Waukegan, IL) and Abbott Laboratories (Abbott Park, IL), respectively. Following inspection of the clinical site (July 29-August 1, 2008), FDA Form 483 was not issued. Following the inspection of the analytical facility (July 28-30, 2008), Form FDA 483 was issued (Attachment 1). The firm responded to the inspectional findings by letter dated August 8, 2008 (Attachment 2). The observations and our evaluations follow.

For future studies, Abbott will revise its SOP

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Conclusions:

Following the above inspections, the Division of Scientific Investigations recommends that the data from Study M06-830 be accepted for review.

After you have reviewed this memo, please append it to the original NDA submission.

Jacqueline A. O'Shaughnessy, Ph.D.
Pharmacologist

Abhijit Raha, Ph.D.
Pharmacologist

Final Classification:

Abbott Clinical Pharmacology Research Unit, Waukegan - NAI
Abbott Laboratories, Abbott Park, IL - VAI

cc:

HFD-45/RF
HFD-45/Vaccari
HFD-48/O'Shaughnessy/Raha/Patague/CF
DMEP/Johnson (NDA 22-224)
HFR-CE650/McCullough
Draft: AR 9/5/08
Edit: JAO 9/9/08; MFS 9/9/08
DSI 5848 O:\BE\EIRCover\22224abb.fen.doc
FACTS 933996

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863	DATE(S) OF INSPECTION 7/23/2008 - 7/30/2008 FBI NUMBER 3002025546
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED To: Gillian Hodkinson, Divisional Vice President, QA, GPRD	
FIRM NAME Abbott Laboratories, Inc.	STREET ADDRESS 100 Abbott Park Road
CITY, STATE AND ZIP CODE Abbott Park, IL 60064	TYPE OF ESTABLISHMENT INSPECTED Bioequivalence Testing Laboratory
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p> <p>DURING AN INSPECTION OF YOUR FIRM, WE OBSERVED:</p> <p style="text-align: center;">Study Number: M06-830</p> <p style="text-align: center;">"Evaluation of the Relative Bioavailability of Fenofibric Acid from Fenofibric Acid Choline Salt Formulations Manufactured at Two Different Sites and Batch Sizes, and 200 mg Micronized Fenofibrate Capsule"</p> <ol style="list-style-type: none"> 1. The long term frozen storage stability of fenofibric acid in plasma was not demonstrated by comparison to freshly prepared samples. 2. All aspects of study conduct were not documented. For example: <ul style="list-style-type: none"> (a.) _____ (b.) _____ 3. All samples that underwent repeat analysis were not reported in the analytical report in that Table 4 "Reassay History" does not include samples repeated for analytical reasons. 4. The firm's SOP Q-10-10-019 for _____ Although the SOP states that _____ the SOP does not describe _____ 	

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b(4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Robert K. ...	DATE ISSUED 7/30/08
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Abbott

100 Abbott Park Rd.
Abbott Park, Illinois 60064

t 847 938 7808
f 847 938 1181

Attachment 2



August 08, 2008

Scott J. MacIntire
District Director – FDA Chicago District
550 West Jackson Blvd.
Suite 1500
South, Chicago, IL 60661
Tel (312) 596-4200
Fax (312) 596-4187

Dear Mr. MacIntire,

Attached is Abbott Laboratories' response to the Form 483 issued July 30, 2008 as a result of the inspection conducted at the Abbott Facility, located in Abbott Park, Illinois. Consumer Safety Officer Bruce McCullough of the Chicago District, Pharmacologist Dr. Jacqueline O'Shaughnessy, Ph.D. from CDER in Silver Springs, MD, and Pharmacologist Abhijit Raha from CDER in Silver Springs, MD conducted an inspection of the Bioanalytical Laboratories for the TriLipix Bioequivalence Study M06-830 in support of NDA 022224 that was filed with the FDA on December 07, 2007.

We appreciate the importance of the observations in the Form 483 and take them seriously. Corrective actions are in the process of being completed and implemented as detailed in the attached response.

If you have any questions or require additional information, please contact me directly at (847) 938 7808.

Sincerely,

Gillian Hokinson
Divisional Vice President, QA, GPRD

Cc: Dr. C.T. Viswanathan, Ph.D.
FDA (CDER)
Mail Stop HFD-48
Silver Springs, MD 20993

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/s/

Jacqueline OShaughnessy
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PHARMACOLOGIST
Also on behalf of Dr. Raha

Martin Yau
9/12/2008 10:18:55 AM
CSO

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