

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-224

CHEMISTRY REVIEW(S)

10/6/08

TriLipix™ (fenofibric acid)
Delayed-Release Capsule
NDA 22-224

Summary of the Basis for the Recommended Action from
Chemistry, Manufacturing, and Controls

Applicant: Abbott Laboratories
Dept. RA76, Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Indication: Adjunctive therapy to diet, for the treatment of patients with mixed dyslipidemia (in combination with HMG-CoA reductase inhibitors, or as monotherapy), primary hypercholesterolemia (as monotherapy), or hypertriglyceridemia (as monotherapy).

Presentation: The drug product will be supplied in 45 mg and 135 mg TriLipix™ (fenofibric acid) Delayed-Release Capsule packaged in container closure systems that include HDPE bottles with white polypropylene child-resistant caps (90-count), and a clear blister film laminate and push-through foil laminate (7-count).

EER Status: Acceptable

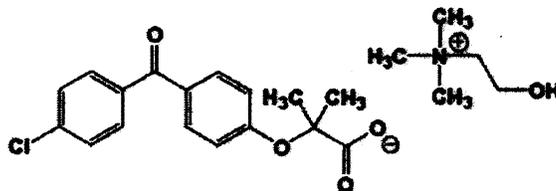
Consult: EA: Categorical exclusion provided in the NDA
Microbiology: N/A
Pharm/Tox: Acceptable
Biopharm: Acceptable
Methods Validation: Acceptable

Original Submission: December 07, 2007

Drug Substance

The drug substance, choline fenofibrate, is choline salt of fenofibric acid. Chemical structure, chemical name, molecular formula and molecular weight of choline Fenofibrate are provided below.

Structure of Choline Fenofibrate



Chemical Name: [Ethanaminium, 2-hydroxy-*N,N,N*-trimethyl-, 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoate (1:1)]
Molecular Formula: $C_{17}H_{14}ClO_4 \cdot C_5H_{14}NO$
Molecular Mass: 421.91 g/mole (choline salt), 318.75 g/mole (free acid)

Choline fenofibrate is freely soluble in water. Fenofibrate is nearly insoluble in water at pH 1-10

b(4)

Choline fenofibrate appears as a white to light yellow powder
Choline fenofibrate is a non-chiral crystalline with no polymorphic forms, and it is not hygroscopic.

Choline fenofibrate is manufactured using fenofibrate as an intermediate. The CMC information for the manufacture of choline fenofibrate is provided in DMF [redacted], DMF holder [redacted], DMF [redacted], DMF holder [redacted], DMF 20895 (choline fenofibrate; DMF holder Abbott Laboratories), and DMF [redacted]. The CMC information provided in the respective DMFs has been reviewed, and all DMFs have been found adequate to support the use of choline fenofibrate in the current application.

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The proposed re-test period of [redacted] for the bulk drug substance, when stored at 25°C/60% RH, is supported by the available and satisfactory stability data.

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Conclusion

Drug substance: The drug substance is satisfactory.

Drug Product

The manufacturing process for choline fenofibrate capsules consists of two major steps. The first step involves manufacturing [redacted] and the second step includes [redacted] (this followed by [redacted])

b(4)

The drug product TriLipix™ (fenofibric acid) Delayed-Release Capsule is supplied in two dosage strengths: 45 mg and 135 mg, equivalent to 45 mg and 135 mg of fenofibric acid (the free acid of choline fenofibrate). The established name of 'fenofibric acid' is used because the dosage strength is correlated with the amount of fenofibric acid, instead of choline fenofibrate. Each TriLipix™ capsule contains a discrete number of enteric coated choline fenofibrate mini-tablets inside a hard gelatin capsule shell. The 45 mg capsule contains [redacted] mini-tablets in [redacted] as 135 mg capsule contains [redacted] mini-tablets.

Each mini-tablet contains [redacted] of choline fenofibrate (equivalent to [redacted] of fenofibric acid), Hypromellose [redacted], povidone, water, hydroxypropyl cellulose, colloidal silicon dioxide, sodium stearyl fumarate, methacrylic acid copolymer [redacted], talc, and triethyl citrate. The CMC information for the manufacture of the choline fenofibrate mini-tablet intermediate is provided in DMF 20896. The DMF has been reviewed and

b(4)

found adequate to support the use of choline fenofibrate mini-tablet intermediate in the current application. The drug product TriLipix™ (fenofibric acid) Delayed-Release Capsule is supplied in high density polyethylene (HDPE) bottles with 38-mm white polypropylene child resistant caps, and in clear blister film laminate with push-through foil laminate (professional sample).

The characteristics of delayed-release capsule is demonstrated by the dissolution profile and controlled by drug release testing at the acid stage (pH 3.5 phosphate medium; at 2 h), and at the buffer stage (pH 6.8 phosphate medium; at 2.5 h, 3.5 h, and 6 h), of the capsules.

The proposed expiry of 24 months for the drug product (45 mg and 135 mg capsules stored at controlled room temperature in HDPE bottles is supported by the available satisfactory stability data.

The proposed expiry of 12 months for the 45 mg capsules, and expiry of 18 months for the 135 mg capsules stored at controlled room temperature in film laminate blisters is supported by satisfactory available stability data.

Conclusion

Drug product: The drug product is satisfactory.

Note

[Redacted area]

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Overall Conclusion:

From a CMC perspective, the application is recommended for approval.

Ali Al-Hakim, Ph.D.
Branch Chief, Branch II
DPA I/ONDQA

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10/1/08

CHEMISTRY REVIEW

NDA 22-224

**TriLipix™
(fenofibric acid)
Delayed-Release Capsule**

Abbott Laboratories

Yvonne Yang, Ph.D.

Office of New Drug Quality Assessment

For

Division of Metabolism and Endocrinology Products

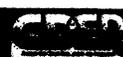


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CHEMISTRY REVIEW

Chemistry Assessment Section

Chemistry Review Data Sheet

1. NDA 22-224
2. REVIEW #: # 1
3. REVIEW DATE: Oct-01-2008
4. REVIEWER: Yvonne Yang, Ph.D.
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
N/A	

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original submission	Dec-07-2007
Amendment 003 (partial response to CMC information request from Filing Communication letter dated Feb-12-2008 including labeling update)	Apr-10-2008
Amendment 004 (final partial response to CMC information request from Filing Communication letter dated Feb-12-2008 for stability data update)	May-07-2008
Amendment 009 (revised drug product specifications to include acid stage sampling for drug release and supporting data)	Aug-07-2008
Amendment 010 (update of drug substance specifications and supporting document)	Aug-25-2008
Amendment 015	Sept-30-2008

7. NAME & ADDRESS OF APPLICANT:

Name: Abbott Laboratories
Address: Dept. RA76, Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157
Representative: Natalie Tolli, B. Pharm, M.S.
Associate Director, GPRA
Telephone: 847-935-8099

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CHEMISTRY REVIEW

Chemistry Assessment Section

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: TriLipix™
b) Non-Proprietary Name (USAN): Choline fenofibrate
c) Code Name/# (ONDQA only): CAS-856676-23-8 (choline fenofibrate)
d) Chem. Type/Submission Priority (ONDQA only):
• Chem. Type: 2
• Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION:

This NDA is submitted as a 505(b)(2) application with the reference listed product being TriCor (fenofibrate) Tablets 48 mg and 145 mg (NDA 21-656, Abbott Laboratories).

10. PHARMACOL. CATEGORY: Lipid Altering Agents II
11. DOSAGE FORM: Capsule, delayed-release
12. STRENGTH/POTENCY: 45 mg and 135 mg
13. ROUTE OF ADMINISTRATION: Oral
14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed
 Not a SPOTS product

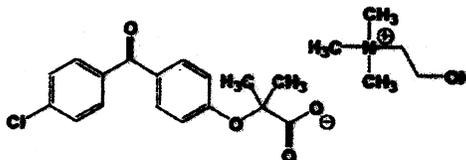
16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Choline fenofibrate: $C_{17}H_{14}ClO_4 \cdot C_5H_{14}NO$

Molecular mass = 421.91 g/mole (choline salt), 318.75 g/mole (free acid)

[Ethanaminium, 2-hydroxy-*N,N,N*-trimethyl-, 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoate (1:1)]

Structure of Choline Fenofibrate



CHEMISTRY REVIEW

Chemistry Assessment Section

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
					Adequate	Review # 1 DARRTS Oct-01-2008	Reviewed by Yvonne Yang
					Adequate	Review # 4 DARRTS Oct-01-2008	Reviewed by Yvonne Yang
					Adequate	Review #1 DARRTS Sept-18-2008	Reviewed by Yvonne Yang
20895	II	Abbott	Choline fenofibrate	1	Adequate	Review #1 DARRTS Sept-18-2008	Reviewed by Yvonne Yang
20896	II	Abbott	Choline fenofibrate Mini-tablet Intermediate	1	Adequate	Review #1 DARRTS Sept-18-2008	Reviewed by Yvonne Yang
					N/A	See Section P.7 of this review for details	
					N/A	See Section P.7 of this review for details	
					N/A	See Section P.7 of this review for details	
					N/A	See Section P.7 of this review for details	
					N/A	See Section P.4 of this review for details	

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¹ Action codes for DMF Table:

1 - DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 - Type 1 DMF

3 - Reviewed previously and no revision since last review

4 - Sufficient information in application

5 - Authority to reference not granted

6 - DMF not available

7 - Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NO.	DESCRIPTION
NDA	21-656 (Abbott Laboratories)	Reference listed product TriCor (fenofibrate) Tablets 48 mg and 145 mg
IND	70,345 (Abbott Laboratories)	IND for the treatment of Type II and IV/V dyslipidemias



CHEMISTRY REVIEW



Chemistry Assessment Section

18. STATUS:

ONDQA:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
EES	Acceptable overall recommendation from OC	May-02-2008	
IVIVC		Sept-26-2008	Arzu Selen (ONDQA Biopharmaceutics)
Biowaiver	Adequate data are provided in the application to support the biowaiver request for the 45 mg	Sept-26-2008	Arzu Selen (ONDQA Biopharmaceutics)
Biopharm	The clinical pharmacology aspects of ABT-335 at 135 mg dose strength were appropriately characterized and this NDA 22-224 is acceptable.	Sept-23-2008	Manoj Khurana Sally Choe
Pharm/Tox	Approval	Aug-28-2008	Indra Antonipillai Karen Davis-Bruno
Tradename Division of Medication Error Prevention and Analysis/Office of Surveillance and Epidemiology (DMEPA/OSE)	<ul style="list-style-type: none"> The medication error prevention staff does not object to the use of the proprietary name, Trilipix, for this product. DMEPA recommends implementation of some label and labeling revisions; in brief, DMEPA recommends the presentation of the proprietary name as Trilipix, in standard upper/lower case presentation 	Aug-21-2008	Richard Abate Kellie Taylor Denise Toyer
PFI consult (DRISK/ODS)		Pending	
Environment Assessment (EA)	Categorical exclusion granted	N/A	Yvonne Yang
Methods Validation	Acceptable	N/A	Yvonne Yang
Microbiology	N/A	N/A	

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CHEMISTRY REVIEW

Chemistry Assessment Section

The Chemistry Review for NDA 22-224

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

NDA 22-166 is recommended for Approval from the standpoint of chemistry, manufacturing and controls pending final labeling.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug Product:

The drug product TriLipix™ is a delayed-release capsule containing the active pharmaceutical ingredient choline fenofibrate. The drug product TriLipix™ (fenofibric acid) Delayed-Release Capsule is supplied in two dosage strengths: 45 mg and 135 mg, equivalent to 45 mg and 135 mg of fenofibric acid (the free acid of choline fenofibrate). The established name of 'fenofibric acid' is used with the proprietary name TriLipix™ because the dosage strength is correlated with the amount of fenofibric acid, instead of choline fenofibrate. Each TriLipix™ capsule contains a discrete number of enteric coated choline fenofibrate mini-tablets inside a hard gelatin capsule shell. The 45 mg capsule contains _____ mini-tablets in _____ the 135 mg capsule contains _____ mini-tablet. Choline fenofibrate mini-tablet (also called choline fenofibrate mini-tablet intermediate) is designed as a delayed-release enteric coated tablet. Each mini-tablet contains _____ of choline fenofibrate (equivalent to 11.25 mg of fenofibric acid), Hypromellose _____ povidone, water, hydroxypropyl cellulose, colloidal silicon dioxide, sodium stearyl fumarate, methacrylic acid copolymer (type C), talc, and triethyl citrate. The CMC information for the manufacture of the choline fenofibrate mini-tablet intermediate is provided in DMF 20896. The CMC information provided in the DMF has been reviewed and found adequate to support the use of choline fenofibrate mini-tablet intermediate in the current application.

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The drug product TriLipix™ (fenofibric acid) Delayed-Release Capsule is supplied in high density polyethylene (HDPE) bottles with 38-mm white polypropylene child-resistant caps, and in clear blister film laminate with push-through foil laminate (professional sample). The 45 mg capsule has a reddish-brown cap imprinted in white

CHEMISTRY REVIEW

Chemistry Assessment Section

ink the Abbott "A" logo and a yellow body imprinted in black ink the number "45"; the 135 mg capsule has a blue cap imprinted in white ink the Abbott "A" logo and a yellow body imprinted in black ink the number "135". Both dosage strengths are available in bottles of 90 in 3-oz HDPE bottles for the 45 mg capsules and in 5-oz HDPE bottles for the 135 mg capsules.

The characteristics of delayed-release capsule is demonstrated by the dissolution profile and controlled by drug release testing at the acid stage (pH 3.5 phosphate medium; at 2 h), and at the buffer stage (pH 6.8 phosphate medium; at 2.5 h, 3.5 h, and 6 h), of the capsules.

The proposed expiry of 24 months for the drug product (for both 45 mg and 135 mg capsules), when stored at controlled room temperature in HDPE bottles, is supported by the available stability data.

The proposed expiry of 12 months for the 45 mg capsules, and expiry of 18 months for the 135 mg capsules, when stored at controlled room temperature in film laminate blisters, is supported by the available stability data.

Drug Substance:

The drug substance in this 505(b) (2) application is choline fenofibrate, the choline salt of fenofibric acid. The drug substance in the reference listed product TriCor (fenofibrate) Tablets (NDA 21-565, Abbott Laboratories) is fenofibrate (1-methylethyl ester of fenofibric acid). Choline fenofibrate is freely soluble in water. Fenofibrate is nearly insoluble in water at pH 1-10.

Choline fenofibrate appears as a white to light yellow powder. Choline fenofibrate is a non-chiral crystalline with no polymorphic forms, and it is not hygroscopic.

Choline fenofibrate is manufactured using fenofibrate as an intermediate. The CMC information for the manufacture of choline fenofibrate is provided in DMF [redacted] DMF holder [redacted] DMF [redacted] DMF holder [redacted] DMF 20895 (choline fenofibrate; DMF holder Abbott Laboratories), and DMF [redacted] DMF holder [redacted]. The CMC information provided in the respective DMF has been reviewed, and all DMFs have been found adequate to support the use of choline fenofibrate in the current application.

The proposed re-test period of [redacted] for the bulk drug substance, when stored at 25°C/60% RH, is supported by the available stability data.

B. Description of How the Drug Product is Intended to be Used

Formulations of fenofibrate have been approved in several products, as adjunctive therapy to diet, for the treatment of patients with mixed dyslipidemia (in combination

CHEMISTRY REVIEW

Chemistry Assessment Section

with HMG-CoA reductase inhibitors, or as monotherapy), primary hypercholesterolemia (as monotherapy), or hypertriglyceridemia (as monotherapy). The applicant is seeking the same indications in the current 505(b)(2) application. Patients will receive one (45 mg or 135 mg) TriLipix™ (fenofibric acid) Delayed-Release Capsule once daily as instructed by the physician. Co-administration with the maximum dose of HMG-CoA reductase inhibitors (statins) has not been evaluated in clinical studies and is therefore not recommended.

C. Basis for Approvability or Not-Approval Recommendation

NDA 22-224 is recommended for Approval from the standpoint of chemistry, manufacturing and controls (CMC) pending final labeling.

CMC information provided to support the application includes the following:

- Adequate CMC information for the drug substance choline fenofibrate
- Adequate CMC information for the drug product TriLipix™ (fenofibric acid) Delayed-Release Capsule
- Acceptable regulatory specifications for the drug substance
- Acceptable regulatory specifications for the drug product
- Sufficient stability data to support the proposed re-test period for the bulk drug substance
- Sufficient stability data to support the proposed expiration dating period for the drug product TriLipix™
- CMC information provided in all supporting DMFs have been reviewed and found adequate to support the current application
- Overall cGMP status was found acceptable by Office of Compliance for all manufacturing and testing facilities

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III. Administrative

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| A. Reviewer's Signature | in DFS |
| B. Endorsement Block | in DFS |
| C. CC Block | in DFS |

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Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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Initial Quality Assessment
Pre-Marketing Assessment Division 1 Branch 2

Division of Metabolism and Endocrinology Products

NDA: 22-224
Applicant: Abbot Laboratories
Stamp Date: 07-DEC-2007
PDUFA Date: 07-OCT-2008
Proposed Proprietary Name: [none]
Established Name: Fenofibric acid (or Choline Fenofibrate)
Dosage form and strength: Delayed release capsule –
45 mg and 135 mg
Route of Administration: oral
Indications: Treatment of dyslipidemia

PAL: Su (Suong) Tran, Branch II/DPA I/ONDQA

ONDQA Fileability: Yes

Comments for 74-Day Letter: Yes, on the last page.

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Initial Quality Assessment
Pre-Marketing Assessment Division 1 Branch 2

CONSULTS/ CMC RELATED REVIEWS	COMMENT
Biopharm/ClinPharm	Review of the PK linearity data.
CDRH	<i>Not Applicable</i>
EA	Categorical exclusion request will be assessed by Primary Reviewer.
EES	EER was sent to Office of Compliance on 03-JAN-2008.
DMETS	<i>Labeling consult request will be sent as part of DMEP's request.</i>
Methods Validation	<i>Validation may be requested of FDA labs after test methods are finalized.</i>
Microbiology	<i>Not Applicable</i>
Pharm/Tox	To be determined by Primary Reviewer.

Summary: [See the discussion in Critical Issues later in this review.]

This is an electronic NDA, filed as a 505(b)(2) application. The RLD is TriCor (fenofibrate) Tablets.

The product is a single-entity, delayed-release, hard-gelatin capsule available in two strengths: 45 mg and 135 mg fenofibric acid. The drug substance is the choline salt of fenofibric acid. Fenofibric acid is the active moiety and primary metabolite of fenofibrate, which is the drug substance of the approved TriCor Tablets (different applicant). In vivo fenofibrate rapidly converts to fenofibric acid, which is responsible for the clinical effect.

The clinical proof of this product is from four Phase 3 clinical studies: M05-748, M05-749, M05-750, and M05-758. Only the 135 mg dosage strength was used in the clinical studies. A biowaiver request is made for the 45 mg dose (see the discussion in Critical Issues later in this review).

Maximum daily dose is 135 mg fenofibric acid.

Route of administration	Oral
Dosage form	Delayed release capsule
Package type	For commercial distribution: Plastic bottles of 90-count with child-resistant caps. For physicians' samples: Foil blisters of 7-count.
Potency	45 mg and 135 mg fenofibric acid.
Color	45 mg: red-brown half and yellow half 135 mg: blue half and yellow half
Shape	Capsule
Coating	None on the final dosage form (capsule)
Size	
Scoring	None
Imprint codes	45 mg: "A" in white ink and "45" in black ink 135 mg: "A" in white ink and "135" in black ink
Symbols	None

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Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Suong Tran
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as we discussed.

Ali Al-Hakim
2/1/2008 03:37:44 PM
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Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : 1415939 FEI : 1415939
ABBOTT LABORATORIES
100/200 ABBOTT PARK RD
ABBOTT PARK, IL 60064

DMF No: AADA:

Responsibilities: FINISHED DOSAGE PACKAGER

Profile : NEC OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-MAY-08
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 2650279 FEI : 3000210838
ABBOTT LABORATORIES
KM 58.0 CARR 2
BARCELONETA, PR 00617

DMF No: 20895 20896 AADA:

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ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Responsibilities: DRUG SUBSTANCE MANUFACTURER
FINISHED DOSAGE MANUFACTURER

Profile : CSN OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 04-JAN-08

Decision : ACCEPTABLE

Reason : BASED ON PROFILE

Profile : NEC OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 31-MAR-08

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI : 3004134577

FOURNIER LABORATORIES IRELAND LTD

AMMGRPVE-CARRIGTWOHILL

COUNTY CORK, , EI

DMF No: ADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile : OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 31-JAN-08

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

b(4)

Establishment : CFN : FEI :

b(4)

DMF No: _____

AADA:

b(4)

Responsibilities: _____

Profile :

OAI Status: NONE

Last Milestone:

OC RECOMMENDATION

Milestone Date:

31-JAN-08

Decision :

ACCEPTABLE

Reason :

DISTRICT RECOMMENDATION

Establishment :

CFN :

FBI : _____

└

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DMF No: _____

AADA:

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Responsibilities: _____

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Profile : _____ OAI Status: NONE **b(4)**
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 31-JAN-08
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION

Establishment : CFN : _____ FEI : _____

✓
 ✓
 ✓

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DMF No: _____ AADA: _____

Responsibilities: _____

Profile : _____ OAI Status: NONE
 Last Milestone: OC RECOMMENDATION
 Milestone Date: 31-JAN-08
 Decision : ACCEPTABLE
 Reason : DISTRICT RECOMMENDATION

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