CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-203

CHEMISTRY REVIEW(S)

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-203 **DATE REVIEWED**: April 26 2001

CHEMISTRY REVIEW #: 5 **REVIEWER**: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	11/12/99	11/12/99	11/23/99
Amendment	04/20/01	04/23/01	04/23/01

NAME & ADDRESS OF APPLICATION:

Abbott Laboratories.
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, IL 60064-6108
Tel: (847)937-6844
Fax: (847)937-8002

DRUG PRODUCT NAME:

Proprietary:	Tricor™
Established:	Fenofibrate tablets
Code Name:	None
Chem. Type/Ther. Class:	1 S

PHARMACOLOGICAL CATEGORY/INDICATION: Lipid-lowing agent

DOSAGE FORM: Tablet

STRENGTHS: 54 mg/tablet, [redacted], and 160 mg/tablet

ROUTE OF ADMINISTRATION: Oral

CONCLUSION AND RECOMMENDATION:
The newly proposed proprietary and established names described in the revised package insert are acceptable from chemistry viewpoint.

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/MSimoneau/SMoore
HFD-820/JSKoepke/CHoiberg
R/D init. by:

File Name: NDA21203N005

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

4 pages

/s/

Chien-Hua Niu
3/27/01 11:03:38 AM
CHEMIST

Stephen Moore
3/27/01 11:09:56 AM
CHEMIST

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ON ORIGINAL

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-203 **DATE REVIEWED**: March 26 2001

CHEMISTRY REVIEW #: 4 **REVIEWER**: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	11/12/99	11/12/99	11/23/99
Amendment	02/19/01	02/20/01	02/21/01

NAME & ADDRESS OF APPLICATION:

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100 Abbott Park Road
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Established:	Fenofibrate tablets
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PHARMACOLOGICAL CATEGORY/INDICATION: Lipid-lowing agent

DOSAGE FORM: Tablet

STRENGTHS: 54 mg/tablet [redacted] and 160 mg/tablet

ROUTE OF ADMINISTRATION: Oral

CONCLUSION AND RECOMMENDATION:

The sponsor has provided 24 months real time stability data in blister and bottle packages to support their request of the [redacted] dating on the bottles and [redacted] on the blisters. Based on the kinetic analysis of these data, a request for an [redacted] expiration dating for Tricor 54 mg, [redacted] and 160 mg tablets packaging in blisters and an [redacted] for tablets packaging in HDPE bottles stored at "controlled room temperature (15 - 30°C) and protected from moisture" should be granted. However, the sponsor should be reminded that the specification for potency of Tricor should be tightened from 90 to 110% to 95% to 105% in accordance with the new stability data when more commercial batches are analyzed.

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/MSimoneau/SMoore
HFD-820/JSKoepke/CHoiberg
R/D init. by:

File Name: NDA21203N004

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

2 pages

/s/

Chien-Hua Niu
3/26/01 03:20:50 PM
CHEMIST

Stephen Moore
3/26/01 03:26:30 PM
CHEMIST

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13 pages

Application: NDA 21203/000
Stamp: 12-NOV-1999
Regulatory Due: 05-SEP-2001
Applicant: ABBOTT LABS
100 ABBOTT PARK RD D491 AP6B1
ABBOTT PARK, IL 600643500
Priority: 3S
Org Code: 510

Action Goal:
District Goal: 14-JUL-2000
Brand Name: TRICOR
(FENOFIBRATE)54 — 160MG
TABLETS
Estab. Name:
Generic Name: FENOFIBRATE

Dosage Form: (TABLET)
Strength: 54 — 160 MG

Application Comment:
FDA Contacts: C. NIU (HFD-510) 301-827-6420 , Review Chemist

Overall Recommendation: ACCEPTABLE on 01-AUG-2000 by EGASM

Establishment: 1411365
ABBOTT LABORATORIES
1401 14TH AND SHERIDAN ROAD
NORTH CHICAGO, IL 60064
DMF No: AADA:
Responsibilities: FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER
Profile: TCM OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	24-JAN-2000				NIU
OC RECOMMENDATION	24-JAN-2000			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment: 1415939
ABBOTT LABORATORIES
100 ABBOTT PARK RD
ABBOTT PARK, IL 600643500
DMF No: AADA:
Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE PACKAGER
Profile: TCM OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	24-JAN-2000				NIU
OC RECOMMENDATION	24-JAN-2000			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

Establishment: 9613828
LABORATOIRES FOURNIER SA
FONTAINE-LES-DIJON, , FR
DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE RELEASE TESTER
Profile: TCM OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	24-JAN-2000				NIU

SUBMITTED TO DO	24-JAN-2000	GMP			EGASM
ASSIGNED INSPECTION '	24-JAN-2000	GMP			EGASM
INSPECTION SCHEDULED	16-MAY-2000		11-MAY-2000		EGASM
INSPECTION PERFORMED	16-MAY-2000		11-MAY-2000		EGASM
DO RECOMMENDATION	01-AUG-2000			ACCEPTABLE	EGASM
OC RECOMMENDATION	01-AUG-2000			INSPECTION ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

Establishment: [redacted]

DMF No:

AADA:

Responsibilities: [redacted]

Profile: CSN

OAI Status: NONE

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	24-JAN-2000				NIU
SUBMITTED TO DO	24-JAN-2000	GMP			EGASM
ASSIGNED INSPECTION '	24-JAN-2000	GMP			EGASM
INSPECTION SCHEDULED	14-MAR-2000				CREHKOPF
INSPECTION PERFORMED	09-MAY-2000		04-MAY-2000		EGASM
DO RECOMMENDATION	22-JUN-2000			ACCEPTABLE	EGASM
OC RECOMMENDATION	23-JUN-2000			INSPECTION ACCEPTABLE DISTRICT RECOMMENDATION	EGASM

APPEARS THIS WAY ON ORIGINAL

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-203 **DATE REVIEWED**: August 23, 2000

CHEMISTRY REVIEW #: 3 **REVIEWER**: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	11/12/99	11/12/99	11/23/99

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Abbott Laboratories.
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, IL 60064-6108
Tel: (847)937-6844
Fax: (847)937-8002

DRUG PRODUCT NAME:

Proprietary:	Tricor™
Established:	Fenofibrate tablets
Code Name:	None
Chem. Type/Ther. Class:	1 S

PHARMACOLOGICAL CATEGORY/INDICATION: Lipid-lowing agent

DOSAGE FORM: Tablet

STRENGTHS: 54 mg/tablet, [redacted] and 160 mg/tablet

ROUTE OF ADMINISTRATION: Oral

CONCLUSION AND RECOMMENDATION:
The sponsor has properly addressed all chemistry deficiencies. Moreover, cGMP inspection of the facilities used for manufacturing the drug substance, drug product, packaging and testing has been completed and found to be acceptable. Thus, the application can be approved from chemistry viewpoint. Nonetheless, the sponsor should be reminded that (1) the test methods are under validation. If any problems or questions arise, their cooperation in finalizing the procedure is required and (2) the proposed established name for TRICOR should be "fenofibrate tablets" as recommended by OPDRA.

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/MSimoneau/SMoore
HFD-820/JGibbs
R/D init. by:

File Name: NDA21203N003

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-203

DATE REVIEWED: July 31, 2000

CHEMISTRY REVIEW #: 2

REVIEWER: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE DATE	DOCUMENT DATE	CDER DATE	ASSIGNED
Original	11/12/99	11/12/99	11/23/99
Amendment	7/12/00	7/13/00	7/14/00

NAME & ADDRESS OF APPLICATION:

Abbott Laboratories.
100 Abbott Park Road
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DRUG PRODUCT NAME:

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DOSAGE FORM: Tablet

STRENGTHS: 54 mg/tablet, [redacted] and 160 mg/tablet

ROUTE OF ADMINISTRATION: Oral

CONCLUSION AND RECOMMENDATION:
The sponsor has properly addressed chemistry deficiencies. Thus, the application can be approved from chemistry viewpoint provided that (1) cGMP inspection of the facility used for manufacturing the drug product is found to be acceptable and (2) the proposed established name for TRICOR by the sponsor is accepted by OPDRA.

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/MSimoneau/SMoore
HFD-820/JGibbs

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

5 pages

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-203 **DATE REVIEWED**: June 6, 2000

CHEMISTRY REVIEW #: 1 **REVIEWER**: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE DATE	DOCUMENT DATE	CDER DATE	ASSIGNED
Original	11/12/99	11/12/99	11/23/99
Amendment	6/1/00	6/5/00	6/7/00
Amendment	6/5/00	6/6/00	6/7/00

NAME & ADDRESS OF APPLICATION: Abbott Laboratories.
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, IL 60064-6108
Tel: (847)937-6844
Fax: (847)937-8002

DRUG PRODUCT NAME:

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DOSAGE FORM: Tablet

STRENGTHS: 54 mg/tablet. [redacted]., and 160 mg/tablet

ROUTE OF ADMINISTRATION: Oral

CONCLUSION AND RECOMMENDATION:
Sufficient information on chemistry, manufacturing and controls of the drug product has been submitted for the NDA. Therefore, the drug product is approvable from chemistry viewpoint provided that (1) cGMP inspection of the facility used for manufacturing the drug product is found to be acceptable, and (2) the deficiencies listed in the letter of chemistry deficiencies are properly addressed.

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/MSimoneau/SMoore

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-203

ENVIRONMENTAL ASSESSMENT and/or FONSI

MEMORANDUM

DATE: August 27, 2001

SUBJECT: Environmental Assesssment for Tricor Tablets (NDA # 21-203)

TO: File of NDA #21-203

FROM: Chien-Hua Niu, Ph.D.

THROUGH: Dr. Stephen Moore, Chemistry Team Leader, HFD-510

As stated in the NDA submission, the new tablet dosage form would be used in place of the existing dosage form of capsules (NDA #19-304), and, therefore, does not increase the use of the active moiety. Pursuant to 21 CFR 25.31(a), the sponsor claims a categorical exclusion regarding the environmental assessment when the action of this NDA does not increase the use of the active moiety.

The categorical exclusion from the filling of an environmental assessment is granted.

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/s/

Chien-Hua Niu
8/27/01 01:56:54 PM
CHEMIST

Stephen Moore
8/27/01 02:26:42 PM
CHEMIST

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/s/

Chien-Hua Niu
5/1/01 09:04:40 AM
CHEMIST

Stephen Moore
5/1/01 10:18:33 AM
CHEMIST

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ON ORIGINAL