

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-151

**ADMINISTRATIVE
DOCUMENT(S)**



05-Oct-2001 12:45:12PM

ACTION ITEM

Priority: Medium

Due Date: 28-Apr-2001

Tracking Number: 2001.101.00012 Request Type: Clearance Request

Attention: HFD-110 101 Return By: 28-Apr-2001

Document Date: 29-Mar-2001 **Receipt Date:** 05-Oct-2001

Requested Due Date: 01-Dec-2001

Consulted By: Office of Generic Drugs (OGD)

Contact: Harvey Greenberg

Phone: 7-5862 **AX:**

E-Mail Address:

Subject: Diltiazem Hydrochloride

Action Requested: The amount of _____ exceeds the maximum concentration previously approved in an oral drug product. The application has been accepted for filing and the firm has provided information to support the amount of _____. Please provide a pharm/tox review.

Comment:

Use the space below to indicate the action taken

APPEARS THIS WAY
ON ORIGINAL

RECORD OF TELEPHONE CONVERSATION

<p>The following information was requested by the Agency.</p> <p>Regarding the amendment submitted on March 3, 2003, you replaced two responses (A4 and A5) from the minor amendment submitted on February 26, 2002. The agency understands the first new response (A4), but it seems the second response (A5) is almost exactly the same. Please clarify why the A5 response was changed.</p> <p>The firm stated the second response (A5) was restated for litigation purposes, with a slight change in the phrasing.</p> <p>Firm Participant: Marcy McDonald FDA Participants: A.Langkowski, Ph.D. Meeting recorder: T.Palat, PharmD</p>	DATE: 24-March-2003
	APPLICATION NUMBER 76-151
	TELECON
	INITIATED BY OGD
	PRODUCT NAME Diltiazem HCl
	Firm Name: Tor Pharm
	NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Marcy McDonald
	TELEPHONE NUMBER 847-573-9999 x223
	SIGNATURE

Orig: ANDA 76-151
 Cc: Division File
 Chem. II telecon binder

V:\FIRMSNZ\TORPHARM\TELECONS\76151.032403.doc

**APPEARS THIS WAY
ON ORIGINAL**

Pharm

Redacted 7

**Page(s) of trade
secret and /or
confidential
commercial
information**

Telecon Record

Date: 06/29/01

ANDA: 76-151

Firm: Torpharm

Drug: Diltiazem HCl Extended-release Capsules, 120 mg, 180 mg and 240 mg

FDA Participants: Beth Fritsch

Industry Participants: Esther Barber

Phone #: 416-675-8394

Agenda: Discuss Torpharm's progress concerning the Refuse to Receive letter

Esther said that Torpharm is currently reformulating their product. She wants to know if _____ g of _____ is acceptable as an inactive ingredient. I searched the COMIS database. The level is acceptable.

Esther hopes to send the response to the refuse to receive letter within the next month.

8/14/01 Left message for Esther Barber. Need additional information.

8/14/01 Told Esther that Mary Fanning would like to see chronic toxicity and carcinogenicity data for the " _____ as a group." She would also like the firm to provide reasoning that _____ is safe based on the chronic data of the other compounds.

8/30/01 Received additional pharm/tox data

9/7/01 Mary Fanning stated that the application contained sufficient pharm/tox data for filing purposes.

9/7/01 Called Apotex. Left message for Marcy McDonald. We need a new form 356h stating that Aventis is the Holder of the Approved Application.

9/13/01 Received the revised 356h form.

**APPEARS THIS WAY
ON ORIGINAL**

Telecon Record

Date: 06/29/01

ANDA: 76-151

Firm: Torpharm

Drug: Diltiazem HCl Extended-release Capsules, 120 mg, 180 mg and 240 mg

FDA Participants: Beth Fritsch

Industry Participants: Esther Barber

Phone #: 416-675-8394

Agenda: Discuss Torpharm's progress concerning the Refuse to Receive letter

Esther said that Torpharm is currently reformulating their product. She wants to know if _____ of _____ is acceptable as an inactive ingredient. I searched the COMIS database. The level is acceptable.

Esther hopes to send the response to the refuse to receive letter within the next month.

APPEARS THIS WAY
ON ORIGINAL

1.1

CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: 09/10/01

DUE DATE: 12/14/01

OPDRA CONSULT #: 01-0204

TO: Peter Rickman
Acting Director, Division of Labeling and Program Support, Office of Generic Drugs
HFD-610

THROUGH: Harvey Greenberg
Project Manager
HFD-615

PRODUCT NAME:
Dilt CD (Diltiazem Hydrochloride
Extended-Release Capsules, USP)
120 mg, 180 mg, 240 mg, 300 mg

MANUFACTURER: TorPharm

ANDA#: 76-151

SAFETY EVALUATOR: Nora Roselle, Pharm.D.

SUMMARY: In response to a consult from the Office of Generic Drugs, Labeling Review Branch (HFD-613), OPDRA conducted a review of the proposed proprietary name "Dilt CD" to determine the potential for confusion with approved proprietary and established names as well as pending names.

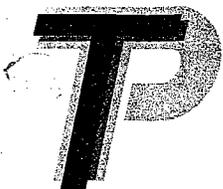
OPDRA RECOMMENDATION:

OPDRA has no objection to the use of the proprietary name, Dilt CD. This name must be re-evaluated approximately 90 days prior to the expected approval of the ANDA. A re-review of the name prior to ANDA approval will rule out any objections based upon approvals of other proprietary names/NDA's from the signature date of this document.

Jerry Phillips
Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

Jerry Phillips / 12-12-01
Martin Himmel, M.D.
Deputy Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

11-27-01



Tor Pharm

COVER LETTER

NC
NEW CORRESP

REFUSE TO FILE AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending its ANDA for Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg in response to the FDA Refuse To File letter dated April 27, 2001 for the ANDA originally submitted on March 29, 2001.

APPEARS THIS WAY
ON ORIGINAL

Esther Barber
Esther Barber
Manager, Regulatory Affairs



July 30, 2001
Date

TORPHARM

**Amendment to ANDA
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg**



TorPharm

76-157

COVER LETTER

REFUSE TO FILE AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending its ANDA for Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg in response to the FDA telephone call from Beth Fritsch dated August 14, 2001 requesting supplementary chronic toxicity data.

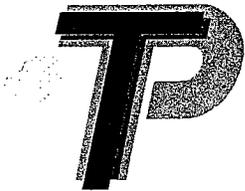
505(b)(2)(A) OK
21-SEP-2001
N/A C
ORIG AMENDMENT
[Signature]

Samantha Law
Samantha Law
Supervisor, Regulatory Affairs

August 29, 2001
Date



TORPHARM
Amendment to ANDA
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg



Tor Pharm Inc.

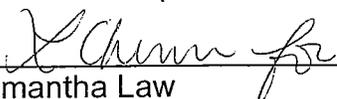
N/am

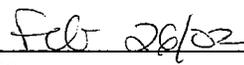
COVER LETTER

ORIG AMENDMENT

MINOR AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 for Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg. The amendment is being submitted in response to the FDA deficiency letter dated January 24, 2002.

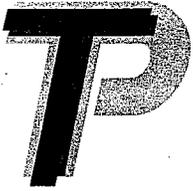

Samantha Law
Supervisor, Regulatory Affairs


Date



TORPHARM

Amendment to ANDA #76-151
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg



Tor Pharm Inc.

ORIG AMENDMENT

N/AM

COVER LETTER

MINOR AMENDMENT

BIOAVAILABILITY

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 for Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg. The amendment is being submitted in response to the FDA deficiency letter dated July 24, 2002.

APPEARS THIS WAY
ON ORIGINAL

Samantha Law

Samantha Law
Supervisor, Regulatory Affairs

October 21, 2002

Date

RECEIVED

OCT 22 2002

OGD / CDER

TORPHARM

Amendment to ANDA #76-151
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg

Handwritten initials and date: 9/10/02



Tor Pharm Inc.

ORIG AMENDMENT
N/A m

COVER LETTER

TELEPHONE AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 for Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg. The amendment is being submitted in response to the FDA telephone call dated January 14, 2003 from Andrew Langowski regarding TorPharm's Minor Amendment dated October 21, 2002.

**APPEARS THIS WAY
ON ORIGINAL**

Wayne Ebanks
Manager, Regulatory Affairs

Jan 24, 2003.
Date

RECEIVED

JAN 28 2003

OGD / CDER

TORPHARM

Amendment to ANDA #76-151
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg



TorPharm Inc.

ORIG AMENDMENT

COVER LETTER

AMENDMENT TO MINOR AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 Diltiazem CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules USP) 120 mg, 180 mg, 240 mg and 300 mg. The amendment is being submitted to withdraw the deficiency responses A.4 and A.5 of the Minor Amendment submitted on February 26, 2002 in the response to the FDA Deficiency Letter dated January 24, 2002. This amendment provides the replacement responses for deficiencies A.4 and A.5. The new responses provide additional clarification regarding Diltiazem HCl Prompt Release _____, _____ (CD) _____, formulation.

APPEARS THIS WAY
ON ORIGINAL



Wayne Ebanks
Manager, Regulatory Affairs

March 3, 2003.
Date

RECEIVED

MAR 04 2003

OGD / CDER TORPHARM

Amendment to ANDA #76-151
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-151

CORRESPONDENCE

APR 27 2001

Apotex Corp.
U.S. Agent for TorPharm
Attention: Marcy Macdonald
50 Lakeview Parkway, Suite #127
Vernon Hills, IL 60061
|||||

Dear Madam:

Please refer to your abbreviated new drug application (ANDA) dated March 29, 2001, submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Diltiazem Hydrochloride Extended-release Capsules USP, 120 mg, 180 mg, 240 mg, and 300 mg.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to receive this ANDA under 21 CFR 314.101(d) (3) for the following reasons:

The concentration of the inactive ingredient _____ in your proposed drug product exceeds the maximum concentration of this inactive ingredient previously approved by the Agency in an oral drug product. Therefore, the proposed drug product cannot be received as an ANDA. Please provide examples of approved drug products administered by the same route of administration which contain this inactive ingredient in the same concentration range or provide information demonstrating that this inactive ingredient in this concentration does not affect the safety of the proposed drug product.

Please provide three additional copies of draft labels and labeling for the archival copy. To be in compliance with 21 CFR 314.94(a) (8) (ii), you must provide four copies of the draft labels and labeling in the archival copy of the application. In the future, please include four copies of the draft labels and labeling in both the archival and review copies of the application.

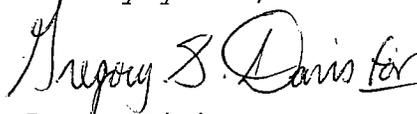
Please provide original signatures for the field copy certification, debarment certification, and U.S. Agent letter of authorization.

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

Beth Fritsch
Project Manager
(301) 827-5862

Sincerely yours,



Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research



50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

SEP 12 2001

Office of Generic Drugs, CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

NEW CORRESP

REQUEST FOR ADDITIONAL INFORMATION

RE: Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Tablets USP)
120 mg, 180 mg, 240 mg and 300 mg
ANDA 76-151

To Whom It May Concern:

As per the telephone conversation with Beth Fritsch of OGD, Regulatory Support, September 7, 2001, Apotex Corp. is forwarding a revised 356h form reflecting the correct name of the innovator.

Please feel free to contact me if you have any further questions.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223



SENDING THE NOTICE

In accordance with 21 CFR 314.95(a):

- Send notice by U.S. registered or certified mail with return receipt requested to each of the following:
 - 1) Each owner of the patent or the representative designated by the owner to receive the notice;
 - 2) The holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval.
 - 3) An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance.

DOCUMENTATION OF NOTIFICATION/RECEIPT OF NOTICE

You must submit an amendment to this application with the following:

- In accordance with 21 CFR 314.95(b), provide a statement certifying that the notice has been provided to each person identified under 314.95(a) and that notice met the content requirements under 314.95(c).
- In accordance with 21 CFR 314.95(e), provide documentation of receipt of notice by providing a copy of the return receipt or a letter acknowledging receipt by each person provided the notice.
- A designation on the exterior of the envelope and above the body of the cover letter should clearly state "PATENT AMENDMENT". This amendment should be submitted to your application as soon as documentation of receipt by the patent owner and patent holder is received.

DOCUMENTATION OF LITIGATION/SETTLEMENT OUTCOME

You are requested to submit an amendment to this application that is plainly marked on the cover sheet "PATENT AMENDMENT" with the following:

- If litigation occurs within the 45-day period as provided for in section 505(j)(4)(B)(iii) of the Act, we ask that you provide a copy of the pertinent

notification.

- Although 21 CFR 314.95(f) states that the FDA will presume the notice to be complete and sufficient, we ask that if you are not sued within the 45-day period, that you provide a letter immediately after the 45 day period elapses, stating that no legal action was taken by each person provided notice.
- You must submit a copy of a court order or judgement or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information. We ask that this information be submitted promptly to the application.

If you have further questions you may contact Gregg Davis, Chief, Regulatory Support Branch, at (301) 827-5862.

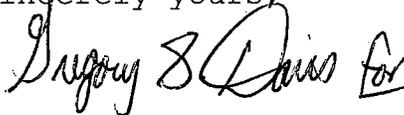
We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Bonnie McNeal
Project Manager
(301) 827-5849

Sincerely yours,



Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research



50 LAKEVIEW PARKWAY • SUITE 127 • VERNON HILLS • ILLINOIS 60061 • TEL: (847) 573-9999 • FAX: (847) 573-1001

October 15, 2001

NEW CORRESP

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

PATENT AMENDMENT

RE: ANDA 76-151
Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120, 180, 240 and 300 mg
Patent # 5286497, 5439689, 5470584, 4894240, 5002776, 5364620

To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm is submitting proof of patent notification to the patent holders.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads 'Marcy Macdonald'.

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223





March 15, 2002

Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
7500 Standish Place
Rockville, MD 20855

3/23/02
P.M.P. 2
NAT
NC

NEW CORRESP

Notice of Litigation

RE: ANDA No. 76-151
Diltiazem CD Capsules
(Diltiazem Extended-Release Capsules)
120 mg, 180 mg, 240 mg and 300 mg

To Whom It May Concern:

This is to inform you that a Notice of Complaint has been filed by Biovail Laboratories, Inc ("Biovail") and TWFC, Inc. in relation to U.S. Patents No. 5,286,497, 5,439,689 and 5,470,584 as a result of the paragraph IV certification notice submitted by Torpharm. A copy of the Complaint follows.

Please feel free to contact me if you have any further questions.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

NAT
JM 4/4/02

RECEIVED

MAR 20 2002

OGD / CDER

NAT
4/4/02

March 6, 2003

NEW CORRESP

Office of Generic Drugs, CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NC

**PATENT / LITIGATION
PATENT STATUS UPDATE**

RE: Diltiazem CD Capsules
(Diltiazem Hydrochloride Extended-Release Capsules USP)
120 mg, 180 mg, 240 mg and 300 mg
ANDA No. 76-151

To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm is hereby providing the following Patent / Litigation Status for the above referenced product.

Patent Number	Status
4,894,240	No litigation
5,002,776	No litigation
5,286,497	Litigation currently in discovery stage
5,470,584	Litigation currently in discovery stage
5,364,620	No litigation
5,439,689	Litigation currently in discovery stage

Notice to Patent holders was received by them October 10, 2001. The 30 month stay has therefore not expired.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Director, Regulatory Affairs
Ext. 223

RECEIVED

MAR 11 2003

OGD / CDER

Labeling review
drafted 10/28/03
A. Vazza



TorPharm INC.

Office of Generic Drugs
CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT **FPL**
N/A M

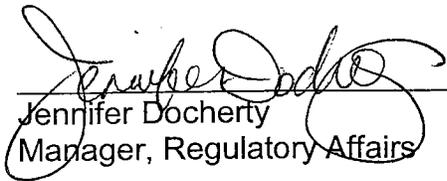
Re: Minor Amendment for DILT-CD (Diltiazem Hydrochloride Extended-Release Capsules, USP) (Once-a-day dosage) Tablets 120 mg, 180 mg, 240 mg and 300 mg ANDA# 76-151

To Whom It May Concern:

TorPharm Inc., 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 DILT-CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules, USP) (Once-a-day dosage) 120 mg, 180 mg, 240 mg and 300 mg. This amendment is being submitted to introduce the 90s pack size to each strength as well as provide final printed labelling.

Should you have any questions or concerns regarding the enclosed, please do not hesitate to contact me at (416) 675-8406 or by fax at (416) 675-0340.

Sincerely

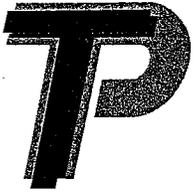

Jennifer Docherty
Manager, Regulatory Affairs

October 20, 2003
Date

RECEIVED
OCT 21 2003
OGD/CDER
TORPHARM INC.

Amendment to ANDA 76-151
DILT-CD (Diltiazem Hydrochloride
Extended-Release Capsules, USP
(Once-a-day dosage)
120 mg, 180 mg, 240 mg and 300 mg

Handwritten initials and date:
MVC
10/24



TorPharm Inc.

Office of Generic Drugs
CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT

N/AF

To Whom It May Concern:

Re: Final Printed Labeling Amendment for DILT-CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules, USP) (Once-a-day dosage) 120 mg, 180 mg, 240 mg and 300 mg ANDA# 76-151

TorPharm Inc., 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 76-151 DILT-CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules, USP) (Once-a-day dosage) 120 mg, 180 mg, 240 mg and 300 mg in response to the FDA Deficiency Letter dated November 4, 2003.

Should you have any questions or concerns regarding the enclosed, please do not hesitate to contact Jennifer Docherty at (416) 675-8406 or by fax at (416) 675-0340.

Sincerely,



Shawn Shirazi
Director, Research and Development

Dec 10, 2003

Date

TORPHARM INC.

**Amendment to ANDA 76-151
DILT-CD (Diltiazem Hydrochloride
Extended-Release Capsules, USP
(Once-a-day dosage)
120 mg, 180 mg, 240 mg and 300 mg**

RECEIVED

DEC 11 2003

OGD/CDEH



Tor Pharm Inc.

April 14, 2004

Office of Generic Drugs
CDER, FDA
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

4/19/04
KQD
Given to
Cherik
All

ORIG AMENDMENT
NIAW

To Whom It May Concern:

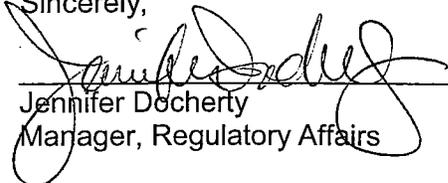
Re: **MINOR AMENDMENT – CHEMISTRY AND MANUFACTURING**
DILT-CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules, USP)
(Once-a-day dosage) 120 mg, 180 mg, 240 mg and 300 mg
ANDA No. 76-151

TorPharm Inc. is hereby submitting a Minor Amendment for DILT-CD Capsules (Diltiazem Hydrochloride Extended-Release Capsules)(Once-a-day dosage) 120 mg, 180 mg, 240 mg, and 300 mg for ANDA No. 76-151. The Amendment is being submitted in response to the FDA Minor Deficiency Letter dated May 12, 2003. The Amendment is also being submitted to update the in process testing specifications for the Diltiazem Hydrochloride CD Type I and III ——— This Amendment is submitted in triplicate (Archival, Review, and Field copies), and contains one volume. The required Field Copy Certification can be found in the last section of the Amendment.

Please note that, although this Minor Deficiency Letter was signed and dated by the FDA on May 12, 2003, neither TorPharm Inc nor our U.S. Agent, Apotex Corp. in Chicago have any record of receiving this letter last year. Until recently, TorPharm Inc had been anticipating approval of our ANDA on April 10, 2004, which was the date of expiry of our 30-month stay. On February 26, 2004, I contacted Ted Pallet, Project Manager at OGD to verify the approval status of the ANDA, at which time I learned of this outstanding Chemistry and Manufacturing Deficiency; hence our delayed response time.

We would appreciate your earliest possible attention to the review of this Minor Amendment. Should you have any questions or concerns regarding the enclosed, please do not hesitate to contact me at (416) 675-8406, by fax at (416) 675-0340 or by email at jdochert@apotex.com.

Sincerely,



Jennifer Docherty
Manager, Regulatory Affairs

cc: Marcy Macdonald, Apotex Corp.

RECEIVED

APR 15 2004

OGD / CDER