CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75611

CORRESPONDENCE

ANDA 75-611

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

APR 21 1999

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Famotidine Tablets USP, 20 mg and 40 mg

DATE OF APPLICATION: March 29, 1999

DATE (RECEIVED) ACCEPTABLE FOR FILING: March 31, 1999

You have filed a Paragraph IV patent certification, in accordance with 21 CFR 314.94(a)(12)(i)(A)(4) and Section 505(j)(2)(A)(vii)(IV) of the Act. Please be aware that you need to comply with the notice requirements, as outlined below. In order to facilitate review of this application, we suggest that you follow the outlined procedures below:

CONTENTS OF THE NOTICE

You must cite section 505(j)(2)(B)(ii) of the Act in the notice and should include, but not be limited to, the information as described in 21 CFR 314.95(c).

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 final order or judgement from which no appeal may be taken (which might not be the one from the District Court), 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 Harvey Greenberg, Acting 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:

Kassandra Sherrod
Project Manager
(301) 827-5849

Sincerely yours,

/s/ for

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-611
DUP/Jacket
Division File
Field Copy
HFD-610/R.West
HFD-92
HFD-615/M.Bennett

Endorsement: HFD-615/HGreenberg, Acting Chief, RSB H Greenberg 4/14/99 date
HFD-615, GDavis, CSO G Davis 4/15/99 date
HFD-645, BArnwine, Sup. Chem. _____ date
Word File v:\firmsnz\torpharm\ltrs&rev\75611.ack
FT/mjl/4/14/99
ANDA Acknowledgment Letter!

APOTEX CORP.

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

March 29, 1999

505(j)(2)(A) OK
Davis
04/15/99
Gregory S. Davis

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

RE: Famotidine Tablets USP 20 mg and 40 mg
Original Abbreviated New Drug Application

To Whom It May Concern:

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, as amended September 24, 1994, Apotex Corp., as the U.S. agent for TorPharm, a Division of Apotex Inc. of Ontario, Canada, hereby submits an original abbreviated new drug application (ANDA) for Famotidine Tablets USP 20 mg and 40 mg.

We are submitting an archival copy under a blue cover (6 volumes), a chemistry review and an additional copy of the analytical methods section under a red cover, and the bioavailability/bioequivalence review section under an orange cover. Financial disclosure can be found in Section VI of the submission.

Apotex Corp. hereby certifies that in accordance with 21 CFR 314.94(d)(5), a true field copy of the technical sections of this submission under a burgundy cover is also included as a foreign applicant is submitting this ANDA.

TorPharm will commit to resolve any issues identified in the methods validation process after approval. We appreciate an expeditious review of this application.

Please direct any inquiries regarding this application to me at the address listed above.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director, Regulatory Affairs
Ext. 223

APOTEX CORP.

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

May 2, 2000

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

NDA ORIG AMENDMENT

N/AM

MINOR AMENDMENT

RE: ANDA 75-611
Famotidine Tablets USP
20 mg and 40 mg

To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm, is hereby forwarding in duplicate a minor amendment in response to the deficiency letter dated March 28, 2000. We are also forwarding a field copy.

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

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAY 04 2000
OGD

APOTEX CORP.

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

ORIG AMENDMENT
N/AC

November 10, 1999

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

MAJOR AMENDMENT

RE: ANDA 75-611
Famotidine Tablets USP
20 mg and 40 mg

To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm, a Division of Apotex Inc., of Ontario, Canada, is hereby submitting in duplicate a major amendment in response to the deficiency letter dated September 10, 1999.

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

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

6/16/00

APOTEX CORP.

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

June 9, 2000

MINOR AMENDMENT

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

MINOR AMENDMENT

RE: ANDA 75-611
Famotidine Tablets USP
20 mg and 40 mg

To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm, is hereby forwarding in duplicate a minor amendment in response to the deficiency letter dated May 26, 2000. We are also forwarding a field copy.

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

Sincerely,

Marcy Macdonald
(KK)

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223

jas 8/23/00

APOTEX CORP.

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

ORIG AMENDMENT

N/Am

August 14, 2000

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

MINOR AMENDMENT

RE: ANDA 75-611
Famotidine Tablets USP
20 mg and 40 mg

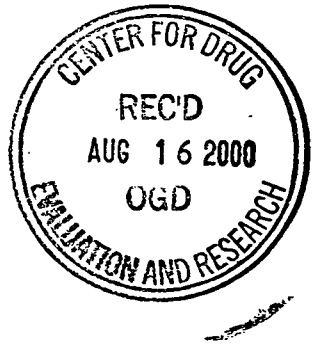
To Whom It May Concern:

Apotex Corp., as the U.S. agent for TorPharm, is hereby forwarding in duplicate a minor amendment in response to the deficiency letter dated July 26, 2000. If you have any further questions, please do not hesitate to contact me. Also included is a field copy.

Sincerely,

Marcy Macdonald

Marcy Macdonald
Associate Director
Regulatory Affairs
Ext. 223



Tor Pharm Inc.

COVER LETTER ORIG AMENDMENT

MINOR AMENDMENT N/AM

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 75-611 for Famotidine Tablets USP 20 mg and 40 mg. The amendment is being submitted in response to the FDA telephone call from Damaris Maldonado on June 12, 2001.

Esther Barber
Esther Barber
Regulatory Affairs Manager

CENTER FOR DRUG EVALUATION AND RESEARCH
JUN 26 2001
OGD

June 22, 2001
Date

TORPHARM

Amendment to ANDA #75-611
Famotidine Tablets USP
20 mg and 40 mg

50 Steinway Blvd., Etobicoke, Ontario, Canada M9W 6Y3 Phone: (416) 675-0338 Fax: (416) 675-0340

Tor Pharm Inc.

NDA ORIG AMENDMENT

N/Am1

COVER LETTER

MINOR AMENDMENT

TorPharm, 50 Steinway Boulevard, Etobicoke, Ontario, Canada, M9W 6Y3, is hereby amending ANDA number 75-611 for Famotidine Tablets USP 20 mg and 40 mg. The amendment is being submitted in response to the FDA Deficiency Letter dated November 9, 2000.

Esther Barber
Esther Barber
Regulatory Affairs Manager

CENTER FOR DRUG EVALUATION AND RESEARCH
MAY 18 2001
OGD

May 17, 2001
Date

TORPHARM

Amendment to ANDA #75-611
Famotidine Tablets USP
20 mg and 40 mg

50 Steinway Blvd., Etobicoke, Ontario, Canada M9W 6Y3 Phone: (416) 675-0338 Fax: (416) 675-0340