CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 76-894/S-004

Name: Torsemide Tablets, 5 mg, 10 mg, 10 mg, and 100 mg

Sponsor: Apotex Corp.

Approval Date: April 10, 2008

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-894/S-004

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APPLICATION NUMBER:

ANDA 76-894/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-894/S-004

Apotex Corp.
U.S. Agent for Apotex Inc.
Attention: Kiran Krishnan
2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your supplemental new drug application dated February 15, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Torsemide Tablets, 5 mg, 10 mg, 20 mg, and 100 mg.

The supplemental application, submitted as "Supplement - Changes Being Effected in 30 days", provides for a change in the compression parameters (hardness and thickness) for the 5 mg, 10 mg, and 20 mg strengths to produce product having consistent and desired dissolution profile.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for the approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Paul Schwartz
4/10/2008 12:17:20 PM
Signed for R. Patel

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APPLICATION NUMBER:

ANDA 76-894/S-004

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

February 15, 2008

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

To whom it may concern:

Re: SUPPLEMENT – CHANGES BEING EFFECTED IN 30 DAYS
Torsemide Tablets 5 mg, 10 mg, 20 mg and 100 mg
ANDA No. 76-894
Change in Compression Parameters (Hardness and Thickness)

Apotex Inc. is submitting a Supplement – CBE-30 for Torsemide Tablets, ANDA No. 76-894, in accordance with the Guidance for Industry - Changes to an Approved NDA or ANDA Section VII.C.1 (a) for a change in process parameter to the drug product.

Specifically, the change involves:

- A change in the compression parameters (hardness and thickness) for the 5 mg, 10 mg and 20 mg strengths. The new compression ranges will produce product having consistent and desired dissolution profile.

The proposed change does not impact the 100 mg strength since it is manufactured from ———————— and uses different compression ranges.

A summary of the changes along with an explanation of the supporting data is attached as Addendum 1.

This supplement is submitted in the eCTD format. A letter of non-repudiation agreement has been submitted. Only the relevant sections of the eCTD that are affected by the change are provided in this supplement. A table of contents of those sections that are included in this supplement is attached as Addendum 2.

Please direct any communications regarding this application to Kiran Krishnan at Apotex Corp., by telephone (954) 384-3986 or by fax (954) 349-4233, or for any other concerns, please do not hesitate to contact me by telephone at (416) 401-7889, by fax (416) 401-3809, or email btao@apotex.com.

Sincerely,

Bernice Tao
Director, Regulatory Affairs US

APPEARS THIS WAY
ON ORIGINAL

CBE Routing Form

This form is to accompany all CBE Supplements. Upon completion, File in DFS.

I. To be completed:

LETTER DATE: 2-15-08
APPLICATION: 76-894 SUPPLEMENT(S): 004

Submitted as: ☐ **CBE-Zero** ☒ **CBE-30** ☐ **Labeling CBE**

II. To be completed by the Chemistry/Micro Division Staff:

This qualifies as:

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *
CBE-30	SELECT CBE TYPE	SELECT CBE TYPE
Endorsement: BD; 2-28-08 see below sec. 4 & 5	Endorsement: rb, Feb 29, 2008 see below sec. 4 & 5	Endorsement:

* Div/ Deputy Director Signature needed only when:
1.) CBE is elevated to a PAS or 2.) PM/TL recommend different actions

III. Labeling CBE:

Granted: ☐ Denied: ☐

Team Leader Endorsement:_____ Decision Date:_____

IV. Basis for Decision/Comments:

V. Approval By Inspection:

Upon review at the Team level it was determined that the supportive data provided for the proposed change is sufficient for the approval of the supplement and needs no further input from the primary reviewer.

Changes deemed via TL: Acceptable By-Inspection: ☒ **YES**
Comments/Endorsement:
Ben to type the AP letter

VI. Project Manager Chemistry Team: SELECT TEAM #

Prepare letter and notify applicant by telephone when CBE is denied because it is a Prior Approval Supplement. DATE:_____

Notify applicant by telephone that inappropriate CBE category used. DATE: _____

Request that applicant withdraw supplement, and submit the changes with the next Annual Report. DATE: _____

VII. Document Room: Record appropriate CBE code and file in archival submission.
Granted (GR); Doesn't qualify, inappropriate CBE category (DC); Doesn't qualify, it's AR (DA); Doesn't qualify, it's a PAS (DN)

FINAL DECISION:GRANTED (GR)____ DATE: 2-29-08

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Gururaj Bykadi
2/29/2008 12:59:38 PM