ANDA 078986

OFFICE OF GENERIC DRUGS

Office of Generic Drugs (HFD–600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville,MD 20855
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Apotex Corp.
U.S. Agent for Apotex Inc.
ATTN: Kiran Krishnan

TEL: (954) 384-3986

FAX: (954) 349-4233

FROM: Robert Gaines

FDA CONTACT PHONE: (240) 276-8495

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated June 29, 2007, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Carbamazepine Extended-Release Capsules, 100 mg, 200 mg and 300 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078986

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 29, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Carbamazepine Extended-Release Capsules, 100 mg, 200 mg and 300 mg.

Reference is also made to your amendments dated July 15, October 16, and December 24, 2008; January 8, June 4, June 22, July 24, August 5, and August 17, 2009; January 6, January 20, and May 12, 2010; and February 1, May 12, May 25, October 12, and October 31, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Carbamazepine Extended-Release Capsules, 100 mg, 200 mg and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Carbatrol Capsules 100 mg, 200 mg and 300 mg, respectively, of Shire Development, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted in -

Apparatus	II (paddle) with peak vessels
Speed of Rotation	75 rpm
Medium	Phosphate buffer, pH 6.8
Volume	500 mL (100 mg strength) 750 mL (200 mg strength) 1000 mL (300 mg strength)
Temperature	37°C ± 0.5°C

Specifications:

Time (Hours)	Percent Dissolved
1	30-60
4	70-95
8	Not less than 80

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Carbatrol Capsules, of Shire Development, Inc. (Shire), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,912,013 (the '013 patent), is scheduled to expire on June 15, 2016.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '013 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Carbamazepine Extended-Release Capsules, 100 mg, 200 mg and 300 mg, under this ANDA. You have notified the agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Apotex for infringement of the '013 patent within the statutory 45-day period in the United States District Court for the Eastern District of Texas [Shire LLC v. Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc., Civil Action No. 2:08-cv-265]. This was later consolidated in Shire LLC v. Apotex Inc., Apotex Corp., and Apotex Pharmaceutical Holdings Inc., Civil Action No. 08-3598(SRC)(MAS) in the United States District Court for the District of New Jersey. You have also notified the agency that, pursuant to a settlement agreement, this case was dismissed on November 2, 2009.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory

requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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/

ROBERT L WEST
11/25/2011
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.