CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 201846

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201846

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 April 16, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Azelastine Hydrochloride Nasal Solution (Nasal Spray), 0.15% [0.187 mg (base)/spray], packaged in containers providing 200 metered sprays.

Reference is made to the tentative approval letter issued by this office on July 16, 2012, and to your amendment dated July 16, 2012.

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 Azelastine Hydrochloride Nasal Solution (Nasal Spray), 0.15% [0.187 mg (base)/spray] to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Astepro Nasal Spray, 0.15%, of Meda Pharmaceuticals, Inc. (Meda).

The RLD upon which you have based your ANDA, Meda's Astepro Nasal Spray, 0.15%, 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. 8,071,073 (the '073 patent), is scheduled to expire on June 4, 2028.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '073 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Azelastine HCl Nasal Solution (Nasal Spray), 0.15% [0.187 mg (base)/spray] under this ANDA. You notified the agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '073 patent was brought against Apotex in the United States District Court for the District of New Jersey [Meda Pharmaceuticals Inc. v. Apotex Inc., Apotex Corp., Civil Action No. 3:2012-cv-00361]. It is noted that the '073 patent was not listed when your ANDA was submitted, and therefore litigation with respect to it does not present a bar to approval of your ANDA.

With respect to 180-day generic drug exclusivity, we note that Apotex was a first applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Apotex is eligible for 180 days of generic drug exclusivity for Azelastine Hydrochloride Nasal Solution (Nasal Spray), 0.15% [0.187 mg (base)/spray]. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv) by a first applicant. Please submit correspondence to this ANDA informing the agency of the date you begin marketing this product.

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}

Gregory P. Geba, M.D., M.P.H.
Director
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/

GREGORY P GEBA
08/31/2012