DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-954

Apotex Corp.
U.S. Agent for: Apotex Inc.
Attention: Kiran Krishnan
Associate 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 November 11, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Azelastine Hydrochloride Nasal Solution, (Nasal Spray), 0.1%, [125 mcg (base)/spray], packaged in containers providing 200 metered-dose sprays.

Reference is also made to the tentative approval letter issued by this office on April 30, 2008, and to your amendments dated October 31, 2006; January 11, and November 6, 2008; and March 13, 2009. In addition, we also acknowledge receipt of your correspondence dated April 17, 2009, addressing patent issues associated with this ANDA.

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, 0.1%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Astelin Nasal Spray, 0.1%, of Meda Pharmaceuticals, Inc. (Meda).

The reference listed drug product (RLD) upon which you have based your ANDA, Meda's Astelin Nasal Spray, 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. 5,164,194 (the '194 patent) is scheduled to expire (with pediatric exclusivity added) on May 1, 2011.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '194 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of for Azelastine Hydrochloride Nasal Solution, 0.1%, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Apotex Inc. (Apotex) for infringement of the listed '194 patent. You have notified the agency that Apotex complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '194 patent was initiated against Apotex in the United States District Court for the District of Delaware [MedPointe Healthcare Inc. v. Apotex, Inc. and Apotex Corp., Civil Action No. 06-164]. You have further notified the Agency of a Consent Order and Judgment dated April 21, 2008.

With respect to 180-day generic drug exclusivity for Azelastine Hydrochloride Nasal Solution, 0.1%, we note that Apotex was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '194 patent. Therefore, with this approval, Apotex is eligible for 180 days of generic drug exclusivity for Azelastine Hydrochloride Nasal Solution, 0.1%. Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

We 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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 77-954***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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/

Robert L. West
4/30/2009 08:45:01 AM
Deputy Director, for Gary Buehler