ANDA 216421

ANDA APPROVAL

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

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 29, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy and Children's Allergy).

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on December 19, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act for over-the-counter (OTC) use. Accordingly the ANDA is **approved**, effective on the date of this letter.

We have determined your Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy) to be bioequivalent to the reference listed drug (RLD), Astepro Allergy Nasal Spray, 0.15% (205.5 mcg per spray) (OTC) and your Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Children's Allergy) to be bioequivalent to the reference listed drug (RLD), Children's Astepro Allergy Nasal Spray, 0.15% (205.5 mcg per spray) (OTC), of Bayer Healthcare LLC (Bayer).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated August 24, 2021.

The RLD upon which you have based your ANDA, Bayer's Astepro Allergy Nasal Spray, 0.15% (205.5 mcg per spray) (OTC) and Children's Astepro Allergy Nasal Spray, 0.15% (205.5 mcg per spray) (OTC), is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled

Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,071,073 (the '073 patent)	June 4, 2028
8,518,919 (the '919 patent)	November 22, 2025
9,919,050 (the '050 patent)	November 22, 2025

Your ANDA contains paragraph IV certifications to each of the patents[1], under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy and Children's Allergy), under this ANDA. You have notified the Agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act.

We note that Apotex was granted a Competitive Generic Therapy (CGT) designation for Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy and Children's Allergy). However, Apotex is not a "first approved applicant" for such competitive generic therapies, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because these drug products are eligible for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. See section 505(j)(5)(B)(v)(III)(bb)(BB) of the FD&C Act. Therefore, these drug products are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

With respect to 180-day generic drug exclusivity, we note that Apotex was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy and Children's Allergy). With respect to Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Allergy), the Agency has determined that Apotex has forfeited its eligibility for 180-day exclusivity because Apotex failed to obtain tentative approval within 30 months after the date on which the ANDA was filed.[2] See section 505(j)(5)(D)(i)(IV) of the FD&C Act.

With respect to Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Children's Allergy), Apotex may be eligible for 180 days of generic drug exclusivity. The Agency is not, however, making a formal determination at this time of Apotex's eligibility for 180-day generic drug exclusivity for Azelastine Hydrochloride Nasal Spray, 0.15% (205.5 mcg per spray) (OTC/Children's Allergy). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If

you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The Agency notes that the '073, '919 and '050 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.
[2] Apotex's ANDA was received on June 29, 2021, and did not receive a tentative approval prior to the final approval being issued on today's date. The Agency finds that Apotex's failure to obtain tentative approval within 30 months was not caused by a change in or review of the requirements for approval.

Catherine Poole

Digitally signed by Catherine Poole
Date: 5/29/2024 12:12:46PM
GUID: 5407887a000a1c0c26055eafb8e3258a