



ND 217953 A

ANDA APPROVAL A

Armstrong Pharmaceuticals, Inc.
Attention: Magda Ibedrop
Sr. Supervisor, CMC and Submissions, Reg. Affairs

Dear Magda Ibedrop:

This letter is in reference to your abbreviated new drug application (ND) received for review on December 29, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ipratropium Bromide HF Inhalation Aerosol, 21 mcg/inhalation (17 mcg/actuation).

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 April 4, 2025, and to any amendments thereafter.

We have completed the review of this ND and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ND is approved, effective on the date of this letter. We have determined your Ipratropium Bromide HF Inhalation Aerosol, 21 mcg/inhalation (17 mcg/actuation) to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Atrovent HF Inhalation Aerosol, 21 mcg/inhalation of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), ND 021527.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated February 9, 2024.

The RLD upon which you have based your ANDA, Boehringer's Atrovent HFA® Inhalation Aerosol, 21 mcg/inhalation, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"): A

U.S. Patent Number

Expiration Date

8,474,447 (the '447 patent) A

January 17, 2030 A

Your ANDA contains paragraph IV certification to the '447 patent under section 301(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ipratropium Bromide HFA Inhalation Aerosol, 21 mc /inhalation (17 mc /actuation), under this ANDA. You have notified the Agency that Armstrong Pharmaceutical, Inc. (Armstrong) complied with the requirements of section 301(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Armstrong within the statutory 4-year period.

With respect to 180-day generic drug exclusivity, we note that Armstrong was the first ANDA applicant to submit substantially complete ANDA with paragraph IV certification for Ipratropium Bromide HFA Inhalation Aerosol, 21 mc /inhalation (17 mc /actuation). Therefore, with this approval, Armstrong is eligible for 180 days of generic drug exclusivity for Ipratropium Bromide HFA Inhalation Aerosol, 21 mc /inhalation (17 mc /actuation). FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 301(j)(4)(D) of the FD&C Act. This exclusivity, which is provided for under section 301(j)(4)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing identified in section 301(j)(4)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 60 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 60 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).

We note that Armstrong was granted Competitive Generic Therapy (CGT) designation for Ipratropium Bromide HFA Inhalation Aerosol, 21 mc /inhalation (17 mc /actuation). However, as noted in the February 9, 2024, CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 301(j)(4)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's Orange Book for the RLD at the time of submission of your ANDA.

Please note that if FDA requires Risk Evaluation and Mitigation Strategy (REMS) for listed drug, an ANDA referencing that listed drug also will be required to have REMS. See section 301-1(i) of the FD&C Act.

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 standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 301(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 drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise a official USP monographs. More information on the USP-NF is available on USP's website at <https://www.uspnf.com/>.

ANDA 2179

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REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidelines, 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 list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-and-requirements-and-resources-approved-and-s>.

Sincerely yours,

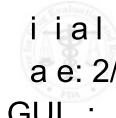
{See appended electronic signature page}

For Kendra S. Stewart, R. Ph., Pharm.D.
CA T, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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