ANDA 213811

ANDA APPROVAL

Amneal Pharmaceuticals NY LLC
U.S. Agent for Amneal Ireland Limited
Attention: Janie Gwinn
Vice President

Dear Janie Gwinn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on January 10, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg.[1]

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 tentative approval letter issued by this office on October 28, 2025, 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. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), QVAR Inhalation Aerosol, 40 mcg and 80 mcg, of Teva Branded Pharmaceutical Products R&D LLC (Teva) NDA - 020911.

The RLD upon which you have based your ANDA, Teva's QVAR Inhalation Aerosol, 40 mcg and 80 mcg, 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
9,463,289 (the '289 patent)	May 18, 2031
9,808,587 (the '587 patent)	May 18, 2031
10,022,509 (the '509 patent)	May 18, 2031

10,022,510 (the '510 patent)	May 18, 2031
10,086,156 (the '156 patent)	May 18, 2031

Your ANDA contains paragraph IV certifications to each of the patents 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 Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg, under this ANDA. You have notified the Agency that Amneal Ireland Limited (Amneal) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Amneal within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Amneal was a first ANDA applicant for Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Amneal may be eligible for 180 days of generic drug exclusivity for Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Amneal failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Amneal's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Amneal begins commercial marketing of Beclomethasone Dipropionate HFA Inhalation, 40 mcg and 80 mcg, or (b) at any time prior to the expiration of the '289, '587, '509, '510, and '156 patents if Amneal has not begun commercial marketing. 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).

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(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 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 Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] We note that the RLD upon which you have based this ANDA, Teva's QVAR Inhalation Aerosol, 40 mcg and 80 mcg, are no longer being marketed in the United States and are currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Teva's QVAR Inhalation Aerosol, 40 mcg and 80 mcg, were not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (84 FR 13298; April 4, 2019). This determination allows the Agency to approve ANDAs for the discontinued drug products.

Sarah Kurtz

Digitally signed by Sarah Kurtz
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