



ND 219602 A

ANDA APPROVAL

Glenmark Pharmaceuticals Inc., US
U.S. Agent for Glenmark Specialty S
Attention: Thomas Callaghan
Executive Director - Regulatory Affairs

Dear Thomas Callaghan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 24, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per 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 May 27, 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 Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Flovent HF Inhalation Aerosol, 44 mcg, of GlaxoSmithKline Intellectual Property Ltd. England ND - 021433.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated July 22, 2024.

We note that Glenmark Specialty S (Glenmark) was granted a Competitive Generic Therapy (CGT) designation for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation. Glenmark is the “first approved applicant” for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Glenmark is eligible for 180 days of CGT exclusivity for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation, under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity begins to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Glenmark, as specified in section 505(j)(5)(B)(v) of the FD&C Act. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C Act, this 180-day

CGT exclusivity will not block approval of other applications until Generic Mark has commenced commercial marketing. I will submit correspondence to this ANDA informing the Agency of the date you begin commercial marketing. I will also submit notice of first commercial marketing via e-mail to the designated Exclusivity Team at CDER-OGD_ET@fd.hhs.gov. This e-mail should be sent through the same you commenced commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 5 5(j)(5)(D)(iv) of the FD&C Act.

I will be aware that, pursuant to this forfeiture rule, you will forfeit your liability for the 18-day CGT exclusivity period for Fluticasone Propionate Inhalation Aerosol US, 44 mg per actuation, if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

I will note that if FDA requires Risk Evaluation and Mitigation Strategy (REMS) for listed drug, an ANDA for generic of that listed drug will also be required to have REMS. See section 5 5-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a manufacturer located in the official United States Pharmacopoeia 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 § 5 1(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 review official USP monographs. More information on the USP-NF is available on USP's website at <https://www.uspnf.com/>.

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 notification requirements, among others. For information on post-approval requirements and recommendations for ANDAs and list of resources for ANDA holders, refer you to <https://www.fda.gov/drugs/bbr/vitd-nw-drug-application-and-requirements-and-resources-post-approved>.

Sincerely yours,

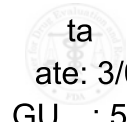
{See appended electronic signature page}

For Kandr S. Stewart, R. h., h rm.D.
CA T, Unit d St t s ublic H lth S rvic
Dir ctor
Offic of R ul tory Op r tions
Offic of G en ric Dru s
C nt r for Dru Ev lu tion nd R s rch

a



Sarah I
Kurtz I



ta s ned b Sarah Kurtz
ate: 3/03/2026 07:32:35AM
GU : 54078879000a1b9e15dd31ed6f0343ca I