ANDA 218854

ANDA APPROVAL

Aurobindo Pharma USA, Inc.
U.S. Agent for Aurobindo Pharma Limited
Attention: Blessy Johns
Vice President

Dear Blessy Johns:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 2, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC).[1]

Reference is also made to the complete response letter issued by this office on October 16, 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 for over-the-counter (OTC) use. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC) to be bioequivalent to the reference listed drug (RLD), Sudafed 24 Hour Extended-Release Tablets, 240 mg, of Kenvue Brands LLC (Kenvue) NDA - 020021.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated September 26, 2023.

We note that Aurobindo Pharma Limited (Aurobindo) was granted a Competitive Generic Therapy (CGT) designation for Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC). Aurobindo is the "first approved applicant" for Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC), as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Aurobindo is eligible for 180 days of CGT exclusivity for Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC), 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 Aurobindo, 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 Aurobindo has commenced commercial marketing. Please submit a correspondence to this ANDA

informing the Agency of the date you begin commercial marketing. Please also submit notice of first commercial marketing via e-mail to the Patent and Exclusivity Team at CDER-OGDPET@fda.hhs.gov. This e-mail should be sent the same day you commence commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 505(j)(5)(D)(iv) of the FD&C Act. Please be aware that, pursuant to this forfeiture rule, you will forfeit your eligibility for the 180-day CGT exclusivity period for Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 240 mg (OTC), if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

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

[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, Kenvue's Sudafed 24 Hour Extended-Release Tablets, 240 mg, is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Kenvue's Sudafed 24 Hour Extended-Release Tablets, 240 mg, was not withdrawn from sale for reasons of safety or effectiveness. FDA will publish this determination in the Federal Register as soon as is practicable. This determination allows the Agency to approve ANDAs for the discontinued drug product.

Paul
Levine

Digitally signed by Paul Levine
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