ANDA 210659

ANDA APPROVAL

Eugia US LLC
U.S. Agent for Eugia Pharma Specialities Limited
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Attention: Apexa Chudasama
Sr. Director, Regulatory Affairs

Dear Apexa Chudasama:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 12, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Alcaftadine Ophthalmic Solution, 0.25% (OTC).

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 March 8, 2022, 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 Alcaftadine Ophthalmic Solution, 0.25% to be bioequivalent to the reference listed drug (RLD), Lastacaft Ophthalmic Solution, 0.25%, of AbbVie Inc. (AbbVie).

The RLD upon which you have based your ANDA, AbbVie's Lastacaft Ophthalmic Solution, 0.25%, 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
8,664,215 (the '215 patent)	December 23, 2027
10,617,695 (the '695 patent)	March 19, 2027

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 Alcaftadine Ophthalmic Solution, 0.25%, under this ANDA. You have notified the Agency that Eugia Pharma Specialities Limited (Eugia) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Eugia for infringement of the '215 patent in the United States District Court for the District of Delaware [Allergan, Inc. et al v. Aurobindo Pharma LTD, Civil Action No. 17-01290]. You have also notified the Agency that this case was dismissed.

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 '695 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

Sarah Kurtz

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