ANDA 217714

ANDA APPROVAL

Cipla USA Inc.
U.S. Agent for Cipla Limited
10 Independence Boulevard, Suite 300
Warren, NJ 07059
Attention: Michele Crawley
Director, Regulatory Affairs

Dear Michele Crawley:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 3, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Esomeprazole Magnesium for Delayed-Release Oral Suspension, 2.5 mg and 5 mg.

Reference is also made to the complete response letter issued by this office on October 2, 2024, 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 Esomeprazole Magnesium for Delayed-Release Oral Suspension, 2.5 mg and 5 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Nexium Delayed-Release for Oral Suspension, 2.5 mg and 5 mg, of AstraZeneca Pharmaceuticals LP (AstraZeneca) NDA - 021957.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated August 16, 2022.

We note that Cipla Limited (Cipla) was granted a Competitive Generic Therapy (CGT) designation for Esomeprazole Magnesium for Delayed-Release Oral Suspension, 2.5 mg and 5 mg. However, Cipla is not a "first approved applicant" for such competitive generic therapy, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because eligibility for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) has previously been forfeited by all applicants for this drug pursuant to section 505(j)(5)(D) of the FD&C Act.[1] See section 505(j)(5)(B)(v)(III)(bb)(CC) of the FD&C Act. Therefore, this drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] Further information may be found on FDA's Paragraph IV Certifications List, available at https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions#List

Anh Pham

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