ANDA 204717/S-004

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Impax Laboratories, LLC
50 Horseblock Road
Brookhaven, NY 11719
Attention: Pavan Kumar Gangavarapu
Vice President, Global Regulatory Affairs

Dear Pavan Kumar Gangavarapu:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on November 5, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Carvedilol Phosphate Extended-Release Capsules, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to the tentative approval letter issued by this office on September 28, 2023, and to any amendments thereafter.

The sANDA, submitted as “Prior Approval Supplement," provides for:

- Amneal Pharmaceuticals Private Limited as an additional drug product manufacturing, packaging, and testing site.
- Assia Chemical Industries Ltd., Teva-Tech site as an alternate drug substance manufacturing, micronization, packaging, release, and stability testing site for the drug product.
- Minor change in formulation.

We have completed the review of this sANDA, as amended, and it is **approved**.

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

Paul Levine

Digitally signed by Paul Levine
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