ANDA 217737

ANDA APPROVAL

Amneal Pharmaceuticals of New York LLC
U.S. Agent for Amneal EU, Limited
Attention: Janie Gwinn
Vice President

Dear Janie Gwinn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 31, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles.

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 any amendments submitted prior to the issuance of this letter.

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 Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Omnipaque Injection, 300 mg Iodine/mL, of GE Healthcare Inc. NDA - 018956.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated October 6, 2022.

We note that Amneal EU, Limited (Amneal EU) was granted a Competitive Generic Therapy (CGT) designation for Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles. Amneal EU is the "first approved applicant" for Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Amneal EU is eligible for 180 days of CGT exclusivity for Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles, 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 Amneal EU, 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 Amneal EU 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 Iohexol Injection USP, 300 mg Iodine/mL Single-Dose Bottles, if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

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 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

Paul Levine

Digitally signed by Paul Levine
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