U.S. FOOD & DRUG ADMINISTRATION

ANDA 217174

ANDA APPROVAL

Amneal Pharmaceuticals LLC
U.S. Agent for Amneal EU, Limited
50 Horseblock Road
Brookhaven, NY 11719
Attention: Janie Gwinn
Senior Director, Regulatory Affairs

Dear Janie Gwinn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 28, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL) Single-Dose Containers.

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 Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL) Single-Dose Containers to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL, of Fresenius Kabi USA, LLC (Fresenius).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated March 21, 2022.

We note that Amneal EU, Limited (Amneal) was granted a Competitive Generic Therapy (CGT) designation for Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL). Amneal is the "first approved applicant" for Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL), as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Amneal is eligible for 180 days of CGT exclusivity for Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL), 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 CGTs (including the commercial marketing of the listed drug) by Amneal, 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 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 Calcium Gluconate in Sodium Chloride Injection, 1000 mg/50 mL and 2000 mg/100 mL (20 mg/mL), if you fail to market these CGTs 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 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
Date: 9/05/2023 11:15:33AM
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