ANDA 219037

ANDA APPROVAL

Milla Pharmaceuticals, Inc.
Attention: Madan Chilakuri
Head of Regulatory Affairs - U.S.

Dear Madan Chilakuri:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 20, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Calcium Gluconate in Sodium Chloride Injection, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), Single-Dose Container.[1]

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, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), Single-Dose Container to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Calcium Gluconate in Sodium Chloride Injection, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), of Fresenius Kabi USA, LLC (Fresenius) NDA - 208418.

The RLD upon which you have based your ANDA, Fresenius's Calcium Gluconate in Sodium Chloride Injection, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
10,130,646 (the '646 patent)	July 25, 2037

The Agency has determined the '646 patent was submitted to the Agency by the new drug application (NDA) holder (a) after the date of the submission of your ANDA, and (b) more than 30 days after the patent was required to be submitted under 21 CFR 314.53. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission was required to submit an amended patent certification to address the '646 patent. You elected not to submit an amended patent certification with respect to the '646 patent.

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 at 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.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] We note that the reference listed drug (RLD) upon which you have based this ANDA on, Fresenius's Calcium Gluconate in Sodium Chloride Injection, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Fresenius's Calcium Gluconate in Sodium Chloride Injection, 1,000 mg/50 mL (20 mg/mL) and 2,000 mg/100 mL (20 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (91 FR 34634; June 8, 2026). This determination allows the Agency to approve ANDAs for the discontinued drug product.

Catherine Poole

Digitally signed by Catherine Poole
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