ANDA 218779

ANDA APPROVAL

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Attention: Shraddha Ruhela
Senior Regulatory Affairs Specialist

Dear Shraddha Ruhela:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 30, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package.

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 Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Selenious Acid Injection USP, 600 mcg/10 mL, of American Regent, Inc. (American Regent), NDA - 209379.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated June 28, 2024.

The RLD upon which you have based your ANDA, American Regent's Selenious Acid Injection USP, 600 mcg/10 mL, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
11,998,565 (the '565 patent)	July 1, 2041
12,150,957 (the '957 patent)	July 1, 2041

Your ANDA contains paragraph IV certifications to each of the patents[1], under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package, under this ANDA. You have notified the Agency that Fresenius Kabi USA, LLC (Fresenius) complied with the requirements of section 505(j)(2)(B) of the FD&C Act.

With respect to 180-day generic drug exclusivity, we note that Fresenius was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package. Therefore, with this approval, Fresenius is eligible for 180 days of shared generic drug exclusivity for Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

We note that Fresenius was granted a Competitive Generic Therapy (CGT) designation for Selenious Acid Injection USP, 600 mcg/10 mL (60 mcg/mL) Pharmacy Bulk Package. However, Fresenius 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 this drug product is eligible for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. See section 505(j)(5)(B)(v)(III)(bb)(BB) 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] The Agency notes that the '565 and '957 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Catherine Poole

Digitally signed by Catherine Poole
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