ANDA 216145

ANDA APPROVAL

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Attention: Dimitar Ivanov
Sr. Manager, Regulatory Affairs

Dear Dimitar Ivanov:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 23, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL) and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package.

Reference is also made to any amendments submitted prior to the issuance of this letter.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated February 18, 2022.

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 Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL) and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL) and 25 mg/5 mL (5 mg/mL), of American Regent, Inc.

We note that Fresenius Kabi USA, LLC (Fresenius) was granted a Competitive Generic Therapy (CGT) designation for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL). Fresenius is the "first approved applicant" for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Fresenius is eligible for 180 days of CGT exclusivity for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity will begin to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Fresenius, 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 Fresenius 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 Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

We also note that Fresenius was granted Competitive Generic Therapy (CGT) designation for Zinc Sulfate Injection USP, 30 mg/10 mL (3 mg/mL) and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package. However, Fresenius is not the "first approved applicant" for such competitive generic therapy, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, your Zinc Sulfate Injection USP, 30 mg/10 mL (3 mg/mL) and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package, are not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with

annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: https://www.fda.gov/media/128163/download).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at: https://www.fda.gov/media/73013/download. Information and Instructions for completing the form can be found at: https://www.fda.gov/media/132152/download. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/opdp-ectd.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[1] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms or active pharmaceutical ingredients manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that

site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at: https://www.fda.gov/media/71211/download. The SPL will be accessible via publicly available labeling repositories.

We remind you that you must continually monitor available labeling resources such as DRUGS@FDA for changes to your reference listed drug's labels and labeling and make any necessary revisions to your labels and labeling. More information on post-approval labeling changes may be found in the guidance for industry titled "Changes to an Approved NDA or ANDA" at: https://www.fda.gov/media/71846/download.

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] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Anh Pham

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