ANDAs 040279/S-030 and 040278/S-027

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Attention: Som Prakash Vats
Senior Regulatory Specialist

Dear Som Prakash Vats:

Please refer to your Supplemental Abbreviated New Drug Applications (sANDAs) received February 2, 2024, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fluorouracil Injection USP, 500 mg/10 mL (50 mg/mL) and 1 g/20 mL (50 mg/mL) Single-Dose Vials (ANDA 040279) and Fluorouracil Injection USP, 2.5 g/50 mL (50 mg/mL) and 5 g/100 mL (50 mg/mL) Pharmacy Bulk Vials (ANDA 040278).

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

We also refer to our letter dated January 5, 2024, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for fluorouracil. This information includes revisions to the Warnings and Precautions and other sections of the labeling to update and incorporate relevant safety information and descriptions of the risks of fluorouracil in patients with dihydropyrimidine dehydrogenase (DPD) deficiency.

These sANDAs provide for revisions to the labeling for fluorouracil and the agreed upon changes to the language included in our electronic communication dated February 23, 2024.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter.

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,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Sarah Kurtz

Digitally signed by Sarah Kurtz
Date: 3/21/2024 09:32:44AM
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