



ANDAs 040278/S-029 and 040279/S-032

## **SUPPLEMENT APPROVAL**

Fresenius Kabi USA, LLC  
Attention: Som Prakash Vats  
Regulatory Technical Manager

Dear Som Prakash Vats:

Please refer to your Supplemental Abbreviated New Drug Applications (sANDAs) received November 21, 2025, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fluorouracil Injection, USP.

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

We also refer to our letter dated October 23, 2025, 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 Injection, USP. This information pertains to the risk of serious adverse reactions related to fluorouracil in patients with dihydropyrimidine dehydrogenase (DPD) deficiency.

These sANDAs provide for revisions to the labeling for Fluorouracil Injection, USP consistent with our October 23, 2025, letter.

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 Kendra S. Stewart, R.Ph., Pharm.D.  
CAPT, United States Public Health Service  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Sarah  
Kurtz

Digitally signed by Sarah Kurtz

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