ANDA 215356

ANDA APPROVAL

Aurobindo Pharma USA, Inc.
U.S. Agent for Aurobindo Pharma Limited
Attention: Blessy Johns
Vice President

Dear Blessy Johns:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 2, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tofacitinib Tablets, 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on September 17, 2025.

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 Tofacitinib Tablets, 5 mg and 10 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xeljanz Tablets, 5 mg and 10 mg, of PF Prism C.V. (PF Prism) NDA - 203214.

The RLD upon which you have based your ANDA, PF Prism's Xeljanz Tablets, 5 mg and 10 mg, is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) 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
RE41783 (the '783 patent)	June 8, 2026

The RLD upon which you have based your ANDA, PF Prism's Xeljanz Tablets, 5 mg and 10 mg, is also subject to a period of exclusivity. As noted above and in the Orange Book, the pediatric exclusivity period associated with the '783 patent is scheduled to expire on June 8, 2026.[1] You have provided a copy of a letter, which notes that PF Prism waives the unexpired pediatric exclusivity associated with the RLD.

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.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] Although your ANDA previously contained a paragraph IV certification to the '783 patent, upon expiration of that patent on December 8, 2025, your certification to the '783 patent is deemed to be a paragraph II certification.

Vinh Phung

Digitally signed by Vinh Phung
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