ANDA 216878

ANDA APPROVAL

Slayback Pharma LLC
301 Carnegie Center, Suite 303
Princeton, NJ 08540
Attention: Praveen Subbappa
Senior Director

Dear Praveen Subbappa:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 12, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tofacitinib Oral Solution, 1 mg/mL.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on September 7, 2022, and to any amendments thereafter.

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 Oral Solution, 1 mg/mL to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xeljanz Oral Solution, 1 mg/mL, of Pfizer Inc. (Pfizer).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated January 5, 2022.

The RLD upon which you have based your ANDA, Pfizer's Xeljanz Oral Solution, 1 mg/mL, is subject to a period of patent protection. The following patent and expiration date 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)	December 8, 2025

Your ANDA contains a paragraph IV certification to the '783 patent, under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tofacitinib Oral Solution, 1 mg/mL, under this ANDA. You have notified the Agency that Slayback Pharma LLC (Slayback) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Slayback for infringement of the '783 patent in the United States District Court for the District of Delaware [Pfizer Inc., C.P. Pharmaceuticals International C.V., PF Prism C.V., PBG Puerto Rico LLC, and PF Prism IMB B.V. v. Slayback Pharma LLC, Civil Action No. 22-cv-00191]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Slayback was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Tofacitinib Oral Solution, 1 mg/mL. Therefore, with this approval, Slayback is eligible for 180 days of generic drug exclusivity for Tofacitinib Oral Solution, 1 mg/mL. 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 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 Slayback was granted a Competitive Generic Therapy (CGT) designation for Tofacitinib Oral Solution, 1 mg/mL. However, Slayback 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

Catherine Poole

Digitally signed by Catherine Poole
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