ANDA 218668

ANDA APPROVAL/TENTATIVE APPROVAL

Edenbridge Pharmaceuticals, LLC
U.S. Agent for Dexcel Pharma Technologies Ltd.
1 Upper Pond Road, Suite D250
Parsippany, NJ 07054
Attention: Jessica Chmielewski
Associate, Regulatory Affairs

Dear Jessica Chmielewski:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 9, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tofacitinib Extended-Release Tablets, 11 mg and 22 mg.

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

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. We have determined your Tofacitinib Extended-Release Tablets, 11 mg and 22 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xeljanz XR Extended-Release Tablets, 11 mg and 22 mg, of Pfizer Inc. (Pfizer). NDA - 208246.

However, we are unable to grant final approval to your Tofacitinib Extended-Release Tablets, 22 mg, at this time because of the exclusivity issue noted below. Therefore, your ANDA is **approved** insofar as it pertains to Tofacitinib Extended-Release Tablets, 11 mg. Your Tofacitinib Extended-Release Tablets, 22 mg, is **tentatively approved**. This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The RLD upon which you have based your ANDA, Xeljanz XR Extended-Release Tablets, 11 mg and 22 mg, of Pfizer, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
9,937,181 (the '181 patent)	March 14, 2034*
11,253,523 (the '523 patent)	March 14, 2034
RE41,783 (the '783 patent)	December 8, 2025
10,639,309 (the '309 patent)	March 14, 2034**

*11 mg strength only
**22 mg strength only

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tofacitinib Extended-Release Tablets, 11 mg and 22 mg, under this ANDA. You have notified the Agency that Dexcel Pharma Technologies Ltd. (Dexcel) 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 Dexcel 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 LL and PF PRISM IMB B.V. v. Dexcel Pharma Technologies Limited, Civil Action No. 23-01304]. You have also notified the Agency that this case was dismissed.

However, we are unable to grant final approval to with respect to the 22 mg strength product at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for Tofacitinib Extended-Release Tablets, 22 mg, and containing a paragraph IV certification. Your ANDA for this strength will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

Upon the foregoing, your ANDA is **approved** insofar as it pertains to the 11 mg strength product. Your 22 mg strength product is **tentatively approved**.

I. Approval of Tofacitinib Extended-Release Tablets, 11 mg

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/.

II. Tentative Approval of Tofacitinib Extended-Release Tablets, 22 mg

Our decision to tentatively approve your Tofacitinib Extended-Release Tablets, 22 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as

appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "MINOR/MAJOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

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.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Sarah Taylor, Regulatory Project Manager, at (301) 796 - 9323.

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

John Ibrahim

Digitally signed by John Ibrahim
Date: 12/16/2024 10:21:57AM
GUID: 542af06d0124375c12e8c1d9fc86e87c