



ANDA 217542

ANDA APPROVAL

Aurobindo Pharma USA, Inc.
U.S. Agent for Aurobindo Pharma Limited
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Attention: Blessy Johns
Vice President

Dear Blessy Johns:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 31, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Baricitinib Tablets, 1 mg and 2 mg.

Reference is also made to the tentative approval letter issued by this office on December 15, 2023, 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 Baricitinib Tablets, 1 mg and 2 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Olumiant Tablets, 1 mg and 2 mg, of Eli Lilly and Company (Eli Lilly).

The RLD upon which you have based your ANDA, Eli Lilly's Olumiant Tablets, 1 mg and 2 mg, 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>U.S. Patent Number</u>	<u>Expiration Date</u>
8,158,616 (the '616 patent)	May 31, 2032
8,420,629 (the '629 patent)	March 10, 2029
9,089,574 (the '574 patent)	November 30, 2032
9,737,469 (the '469 patent)	November 2, 2031
11,045,474 (the '474 patent)	November 30, 2032

11,806,555 (the '555 patent) November 2, 2031

Your ANDA contains paragraph IV certifications to the '616 and '629 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 Baricitinib Tablets, 1 mg and 2 mg, under this ANDA. You have notified the Agency that Aurobindo Pharma Limited (Aurobindo) 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 Aurobindo for infringement of the '616 and '629 patents in the United States District Court for the District of Delaware [Eli Lilly & Co., Incyte Corp. and Incyte Holdings Corp. v. Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc., Civil Action No. 22-01114]. You have also notified the Agency that this case was dismissed.

With respect to the '574, '469, '474 and '555 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Aurobindo was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Baricitinib Tablets, 1 mg and 2 mg. Therefore, with this approval, Aurobindo is eligible for 180 days of shared generic drug exclusivity for Baricitinib Tablets, 1 mg and 2 mg. 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 by any first applicant, as 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).

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



Paul
Levine

Digitally signed by Paul Levine

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