ANDA 215570

ANDA APPROVAL

Synthon Pharmaceuticals, Inc.
P.O. Box 110487
Research Triangle Park, NC 27709
Attention: Gary Strickland
Director, Regulatory Affairs

Dear Gary Strickland:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 24, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg.

Reference is also made to the complete response letter issued by this office on August 12, 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 Palbociclib Tablets, 75 mg, 100 mg, and 125 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ibrance Tablets, 75 mg, 100 mg, and 125 mg, of Pfizer Inc. (Pfizer).

The RLD upon which you have based your ANDA, Pfizer's Ibrance Tablets, 75 mg, 100 mg, and 125 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.S. Patent Number	Expiration Date
10,723,730 (the '730 patent)	February 8, 2034
11,065,250 (the '250 patent)	August 19, 2036
RE47,739 (the '739 patent)	March 5, 2027

Your ANDA contains paragraph IV certifications to each of the patents[1] 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 Palbociclib Tablets, 75 mg, 100 mg, and 125 mg, under this ANDA. You have notified the Agency that Synthon Pharmaceuticals, Inc. (Synthon) 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 Synthon for infringement of the '730 and '739 patents in the United States District Court for the Middle District of North Carolina [Pfizer Inc., Warner-Lambert Company LLC, PF Prism C.V., Pfizer Manufacturing Holdings LLC and PF Prism IMB B.V., v. Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V., Civil Action No. 21-00157] and in the United States District Court for the District of Delaware [Pfizer Inc., Warner-Lambert Company LLC, PF Prism C.V., Pfizer Manufacturing Holdings LLC and PF Prism IMB B.V., v. Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V., Civil Action No 21-00284]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Synthon was a first ANDA applicant for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Synthon may be eligible for 180 days of generic drug exclusivity for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Synthon failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Synthon's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Synthon begins commercial marketing of Palbociclib Tablets, 75 mg, 100 mg, and 125 mg, or (b) at any time prior to the expiration of the '730 and '739 patents if Synthon has not begun commercial marketing. 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

[1] The Agency notes that the '250 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

John Ibrahim

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