ANDA 203640

ANDA APPROVAL

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway
Suite 400
Weston, FL 33326
Attention: Kiran Krishnan
Senior Vice President, Global Regulatory Affairs

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 8, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Nilotinib Capsules, 50 mg, 150 mg, and 200 mg.

Reference is also made to the tentative approval letter issued by this office on June 10, 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 Nilotinib Capsules, 50 mg, 150 mg, and 200 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Tasigna Capsules, 50 mg, 150 mg, and 200 mg, of Novartis Pharmaceuticals Corporation (Novartis).

The RLD upon which you have based your ANDA, Novartis's Tasigna Capsules, 50 mg, 150 mg, and 200 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) 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
8,163,904 (the '904 patent)	February 23, 2029
8,293,756 (the '756 patent)	March 25, 2028
8,389,537 (the '537 patent)	January 18, 2027

8,415,363 (the '363 patent)	January 18, 2027
8,501,760 (the '760 patent)	January 18, 2027
9,061,029 (the '029 patent)	October 7, 2032

With respect to the '904, '756, '537, '363, and '760 patents[1], your ANDA contains paragraph IV certifications 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 Nilotinib Capsules, 50 mg, 150 mg, and 200 mg, under this ANDA. With respect to the '029 patent, your ANDA contains a paragraph IV certification 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 Nilotinib Capsules, 50 mg, under this ANDA. You have notified the Agency that Apotex, Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Apotex within the statutory 45-day period.

With respect to the 150 mg and 200 mg strength drug products, the Agency has determined that information on the '029 patent was submitted to the Agency by the new drug application (NDA) holder (a) after the date of the submission of your ANDA, and (b) more than 30 days after the patent was required to be submitted under 21 CFR 314.53. Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission of the patent was required to submit an amended patent certification to address the '029 patent. You elected not to submit an amended patent certification with respect to this patent for the 150 mg and 200 mg strength drug products.

With respect to 180-day generic drug exclusivity, we note that Apotex was a first ANDA applicant for Nilotinib Capsules, 50 mg, 150 mg, and 200 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Apotex may be eligible for 180 days of generic drug exclusivity for Nilotinib Capsules, 50 mg, 150 mg, and 200 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 Apotex 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 Apotex'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 Apotex begins commercial marketing of Nilotinib Capsules, 50 mg, 150 mg, and 200 mg, or (b) at any time prior to the expiration of the '904, '756, '537, '363, and '760 patents if Apotex 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).

The RLD upon which you have based your ANDA Novartis's Tasigna Capsules, 50 mg, 150 mg, and 200 mg, is also subject to a period of exclusivity. As noted in the Orange Book, the ODE- 171, ODE- 172, and ODE-380 exclusivities are scheduled to expire on September 22, 2025, September 22, 2025, and March 23, 2029 (with pediatric exclusivity added), respectively. You have provided copies of letters from Novartis's counsel, which notes that Novartis waives the unexpired ODE-171, ODE-172, and ODE-380 exclusivity periods with respect to Apotex's ANDA 203640, effective January 18, 2022 and March 16, 2022, respectively.

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] We note that this ANDA currently is eligible for approval the day after expiration of the pediatric exclusivity period. See Section 505A(b)(1)(B) of the FD&C Act. If this day falls on a Saturday, Sunday, or Federal holiday, it will be eligible for approval the next business day.
[2] The Agency notes that the '756 patent was submitted to the Agency after submission of your ANDA for the 150 mg and 200 mg strength drug products. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

Anh Pham

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