ANDA 218544

ANDA APPROVAL

MSN Pharmaceuticals Inc.
U.S. Agent for MSN Laboratories Private Limited
Attention: Dr. Kondal Bairy
Senior Vice President

Dear Dr. Kondal Bairy:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 31, 2023, 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 October 2, 2024, 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) NDA - 022068.

The reference listed drug (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

Your ANDA contains a paragraph IV certifications to the '904, '756, '537, '363, '760, and '029 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 Nilotinib Capsules, 50 mg, 150 mg, and 200 mg, under this ANDA. You have notified the Agency that MSN Laboratories Private Limited (MSN) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against MSN within the statutory 45-day period.

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 Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul Levine

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