ANDA 219227

ANDA APPROVAL

Apotex Corp.
U.S. Agent for Apotex Inc.
Attention: Kiran Krishnan
Senior Vice President, GRA

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 7, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Nintedanib Capsules, 100 mg and 150 mg.

Reference is also made to the tentative approval letter issued by this office on December 23, 2025, 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 Nintedanib Capsules, 100 mg and 150 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ofev Capsules, 100 mg and 150 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), NDA - 205832.

The RLD upon which you have based your ANDA, Boehringer's Ofev Capsules, 100 mg and 150 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
9,907,756 (the '756 patent)	December 7, 2029
10,105,323 (the '323 patent)	December 4, 2029
10,154,990 (the '990 patent)	July 8, 2026

Your ANDA contains paragraph IV certifications to the '756 and '323 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 Nintedanib Capsules, 100 mg and 150 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.

The RLD upon which you have based your ANDA, Boehringer's Ofev Capsules, 100 mg and 150 mg is also subject to periods of exclusivity. As noted above, the pediatric exclusivity period associated with the '990 patent is scheduled to expire July 8, 2026. You have provided a copy of a letter, which notes that Boehringer waives the unexpired pediatric exclusivity.

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

Catherine Poole

Digitally signed by Catherine Poole
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