ANDA 208070

ANDA APPROVAL

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

Dear Dr. Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on October 20, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 mg.

Reference is also made to the complete response letter issued by this office on August 26, 2021, 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 Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Pradaxa Capsules, 75 mg, 110 mg, and 150 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer).

The RLD upon which you have based your ANDA, Boehringer's Pradaxa Capsules, 75 mg, 110 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
7,866,474 (the '474 patent)	March 2, 2028
7,932,273 (the '273 patent)	March 7, 2026
9,034,822 (the '822 patent)	July 20, 2031

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 Dabigatran Etexilate Capsules, 75 mg, 110 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. With respect your Dabigatran Etexilate Capsules, 75 mg and 150 mg, you have notified the Agency that no action for infringement was brought against Apotex within the statutory 45-day period on the '273 patent.

With respect to 180-day generic drug exclusivity, we note that Apotex was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Dabigatran Etexilate Capsules, 110 mg. Therefore, with this approval, Apotex may be eligible for 180 days of shared generic drug exclusivity for Dabigatran Etexilate Capsules, 110 mg. The Agency notes that Apotex failed to obtain tentative approval of its ANDA within 30 months after the date on 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.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Dabigatran Etexilate Capsules, 110 mg, absent forfeiture under section 505(j)(5)(D) of the FD&C Act.[2] 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

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[1] With respect to your Dabigatran Etexilate Capsules, 75 mg and 150 mg, the Agency notes that the '822 patent was submitted to the Agency after submission of your ANDA. With respect to your Dabigatran Etexilate Capsules, 110 mg, the Agency notes that the '474, '273, and '822 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

[2] See also draft guidance for industry on *180-Day Exclusivity: Questions and Answers*, Q. 42, at 26 (Jan. 2017).

John Ibrahim

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