ANDA 215233

ANDA APPROVAL

Syneos Health, LLC
U.S. Agent for Alembic Pharmaceuticals Limited
1030 Sync Street
Morrisville, NC 27560
Attention: Shawna Richards
Manager

Dear Shawna Richards:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on September 29, 2020, 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 our letter dated June 14, 2024, granting final approval to your Dabigatran Etexilate Capsules, 75 mg and 150 mg, and granting tentative approval to your Dabigatran Etexilate Capsules, 110 mg, 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, 110 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Pradaxa Capsules,110 mg of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer).

The RLD upon which you have based your ANDA, Boehringer's Pradaxa Capsules, 110 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

*110 mg strength only

Your ANDA contains paragraph IV certifications to each of the 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 Dabigatran Etexilate Capsules,

110 mg, under this ANDA. You have notified the Agency that Alembic Pharmaceuticals Limited (Alembic) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Alembic 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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Sarah Kurtz

Digitally signed by Sarah Kurtz
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