ANDA 218047

**ANDA APPROVAL**

Apotex Corp
U.S. Agent for Gland Pharma Limited
2400 North Commerce Parkway, Suite 400
Weston, FL 33326
Attention: Kiran Krishnan
SPV, GRA

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 17, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Eribulin Mesylate Injection, 1 mg/2 mL (0.5 mg/mL) Single-dose Vial.

Reference is also made to the complete response letter issued by this office on September 14, 2023, 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 Eribulin Mesylate Injection, 1 mg/2 mL (0.5 mg/mL) Single-dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Halaven Injection, 1 mg/2 mL (0.5 mg/mL), of Eisai Inc. (Eisai).

The RLD upon which you have based your ANDA, Eisai's Halaven Injection, 1 mg/2 mL (0.5 mg/mL), is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| RE46,965 (the '965 patent) | July 8, 2027 |

Your ANDA contains a paragraph IV certification to the '965 patent 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 Eribulin Mesylate Injection,

1 mg/2 mL (0.5 mg/mL) Single-dose Vial, under this ANDA. You have notified the Agency that Gland Pharma Limited (Gland) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Gland 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

John Ibrahim

Digitally signed by John Ibrahim
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