NDA 215033

THERAPEUTIC EQUIVALENCE EVALUATION UNDER 505(j)(7)(A)(v)(I)(bb)

Apotex Inc.
c/o Apotex Corp.
Attention: Kiran Krishnan, PhD
Senior Vice President, Global Regulatory Affairs
2400 North Commerce Parkway, Suite 400
Weston, FL 33326

Dear Dr. Krishnan:

Please refer to your new drug application (NDA) 215033 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for bendamustine hydrochloride injection, 100 mg/4 mL (25 mg/mL).

We also refer to your February 7, 2023, submission, containing a request for a therapeutic equivalence (TE) evaluation as part of a supplement under section 505(j)(7)(A)(v)(I)(bb) of the FD&C Act. In your submission, you requested a TE evaluation with respect to the listed drug Belrapzo (bendamustine hydrochloride injection), 100 mg/4 mL (25 mg/mL) (NDA 205580).

Section 3222 of the Food and Drug Omnibus Reform Act of 2022 (FDORA, enacted December 29, 2022) amended the FD&C Act by adding a new provision to section 505(j)(7)(A). Section 505(j)(7)(A)(v)(I) of the FD&C Act sets forth certain conditions under which FDA evaluates whether an eligible drug submitted in an application pursuant to section 505(b)(2) of the FD&C Act is therapeutically equivalent to a listed drug relied upon in the 505(b)(2) application.

We have completed our TE evaluation and have concluded that your bendamustine hydrochloride injection, 100 mg/4 mL (25 mg/mL) (NDA 215033), is therapeutically equivalent to Belrapzo (bendamustine hydrochloride injection), 100 mg/4 mL (25 mg/mL) (NDA 205580). FDA intends to update its publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") to reflect this evaluation.

If you have any questions, contact Theresa Carioti, Chief Project Management Staff at 301-496-2848 or email Theresa.Carioti@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nicholas Richardson, DO, MPH
Deputy Director (Acting)
Division of Hematologic Malignancies II
Office of Oncologic Disease
Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NICHOLAS C RICHARDSON
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