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RESEARCH**

APPLICATION NUMBER:

215033Orig1s000

OTHER ACTION LETTERS



NDA 215033

TENTATIVE APPROVAL

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) dated and received June 8, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Bendamustine Hydrochloride injection.

This NDA provides for the use of Bendamustine Hydrochloride injection for the following indications:

- treatment of chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established.
- indolent B cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab containing regimen.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, carton and container labeling). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be granted before the period has expired.

The Orphan Drug provisions of the FD&C Act, 21 U.S.C. §§ 360aa-360dd, provide for a grant of seven years of market exclusivity to which a period of pediatric exclusivity may attach. Orphan drug exclusivity blocks approval of any other application for the same drug for the same indication or use. Due to the orphan exclusivity granted to Eagle Pharmaceuticals Incorporation's product, Bendeka, your application for Bendamustine Hydrochloride may not be finally approved for marketing under section 505 of the FD&C Act until the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) and/or exclusivity protection or (2) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as “**REQUEST FOR FINAL APPROVAL**”. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*¹ and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, call CAPT Bernetta L. Lane, DHS, MBA, RN, Senior Regulatory Health Project Manager, at (301) 796-0937.

Sincerely,

{See appended electronic signature page}

Nicole Gormley, MD
Director
Division of Hematologic Malignancies II
Office of Oncologic Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
- Carton and Container Labeling

24 Page(s) of Draft Labeling have been Withheld in Full as b4
(CCI/TS) immediately following this page

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/

NICOLE J GORMLEY
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