CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208194Orig1s000

Trade Name:	BendekaTM Injection, 100 mg/4 mL (25 mg/mL)
Generic Name:	bendamustine hydrochloride
Sponsor:	Eagle Pharmaceuticals, Inc.
Approval Date:	December 7, 2015
Indication:	For treatment of patients with chronic lymphocytic leukemia (CLL) and treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab containing regimen.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208194

NDA APPROVAL

Eagle Pharmaceuticals, Inc.
Attention: Foma Rashkovsky
Senior Director, Regulatory Affairs
50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677

Dear Mr. Rashkovsky:

Please refer to your New Drug Application (NDA) dated February 13, 2015, received February 13, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Bendeka™ (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL).

We also refer to our approval letter dated December 7, 2015 which contained the following error: the incorrect versions of the carton and vial labels were attached.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 7, 2015, the date of the original approval letter.

This new drug application provides for the use of Bendeka (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL), for treatment of patients with chronic lymphocytic leukemia (CLL) and treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) 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 approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

A shelf life of 24 months is granted for Bendeka (bendamustine hydrochloride) Injection, when stored refrigerated at 2 - 8ºC (36 - 46ºF), protected from light.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 208194**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for these indications have orphan drug designation, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

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