# CENTER FOR DRUG EVALUATION AND RESEARCH

# Approval Package for:

***APPLICATION NUMBER:***

## NDA 208194/S-004

**Name:** Bendeka™ (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL).

**Sponsor:** Eagle Pharmaceuticals, Inc.

**Approval Date**: February 6, 2017

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***APPLICATION NUMBER:***

# NDA 208194/S-004

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***APPLICATION NUMBER:***

**NDA 208194/S-004**

# APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208194/S-004

**APPROVAL LETTER**

Eagle Pharmaceuticals, Inc.
Attention: Adrian Hepner, MD, PhD
Chief Medical Officer
50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677

Dear Dr. Hepner:

Please refer to your Supplemental New Drug Application (sNDA) dated November 15, 2016, received November 15, 2016, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bendeka™ (bendamustine hydrochloride) Parenteral 100 mg/4mL (25mg/mL).

This "Prior Approval" supplemental new drug application proposes the following change(s): Increase the long term stability limit for the (b) (4) (b) (4) impurity from NMT (b) (4) to NMT (b) (4) in the drug product specifications.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Rabiya Laiq, Pharm.D., Regulatory Business Process Manager, at (240) 402-6153.

Sincerely,

*{See appended electronic signature page}*

Anamitro Banerjee, Ph.D.
Branch Chief, Branch II (Acting)
Office of New Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

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