

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 208194/S-004

Name: BendekaTM (bendamustine hydrochloride)
Injection, 100 mg/4 mL (25 mg/mL).

Sponsor: Eagle Pharmaceuticals, Inc.

Approval Date: February 6, 2017

CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:
NDA 208194/S-004**

CONTENTS

Reviews / Information Included in this Review
--

Approval Letter	X
Approvable Letter	
Labeling	
Division Director's Memo	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology / Toxicology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology & Biopharmaceutics Review(s)	
Other Review(s)	
Administrative and Correspondence Documents	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 208194/S-004

APPROVAL LETTER



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



Anamitro
Banerjee

Digitally signed by Anamitro Banerjee
Date: 2/06/2017 07:57:58PM
GUID: 5075764700003844b7bc89632228509f

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.