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APPLICATION NUMBER:

208194Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	June 15, 2015
Application Type and Number:	NDA 208194
Product Name and Strength:	Bendeka (bendamustine) 100 mg/4 mL (25 mg/mL)
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eagle Pharmaceuticals, Inc.
Panorama #:	2015-168007
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Bendeka, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) inc ((b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) on February 13, 2015 for this application. The Division of Medication Error Prevention and Analysis (DMEPA) found the name acceptable in OSE Review #2015-49450, dated April 2, 2015. However, on April 14, 2015, the applicant withdrew the name, (b) (4)

Thus, the Applicant submitted the name, Bendeka, for review on April 14, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 14, 2015 and April 20, 2015 proprietary name submission.

- Intended Pronunciation: Ben dek'ah
- Active Ingredient: bendamustine HCL
- Indication of Use: Non-Hodgkins' lymphoma (NHL) and Chronic lymphocytic leukemia (CLL)
- Route of Administration: Intravenous infusion
- Dosage Form: Solution for infusion
- Strength: 100 mg/4 mL (25 mg/mL)
- Dose and Frequency: *Non-Hodgkin's lymphoma (NHL):* 120 mg/m2 administered IV over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. *Chronic lymphocytic leukemia (CLL):* 100 mg/m2 administered IV over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles Requires 50-mL infusion bag of either 0.9% Sodium Chloride Injection, USP (normal saline), 2.5% Dextrose/0.45% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP. (b) (4) The maximum daily dose (dose in a 24-hour period) is 120 mg/m2.
- How Supplied: 100 mg/4 mL (25 mg/mL) multi-use vials for intravenous administration
- Storage: Must be refrigerated at 2ºC to 8ºC (36ºF to 46ºF). 24-month shelf-life and 3-hour ad-mixture stability period.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Bendeka, is derived from the established name. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Seventy-six practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 29, 2015 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4)

Table 1. POCA Search Results	Number of Names

[1]USAN stem search conducted on May 20, 2015.

[2] POCA search conducted on April 24, 2015.

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