CENTER FOR DRUG EVALUATION AND RESEARCH

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

Contents

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.

Highly similar name pair: combined match percentage score ≥70%	5
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	209
Low similarity name pair: combined match percentage score ≤49%	5

2.2.5 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 219 names contained in Table 1 determined 219 names will not pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology (DHP) via e-mail on June 2, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on June 3, 2015, they stated no additional concerns with the proposed proprietary name, Bendeka.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Kevin Wright, OSE project manager, at 301-796-3621.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Bendeka, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 14, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

[3] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Bendeka Study (Conducted on *May 4, 2015*)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Bendeka 200 mg IV over 10 min. today Outpatient Prescription: Bendeka Bring to Clinic #4	Bendeka Bring to clinic #4

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

246 People Received Study
76 People Responded

Study Name: Bendeka

Total	**29**	**22**	**25**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**

BEDBECA	0	1	0	1
BEDECKA	0	2	0	2
BEDEKA	0	0	1	1
BENDEBA	2	0	0	2
BENDECA	0	11	0	11
BENDECCA	0	4	0	4
BENDECKA	0	2	0	2
BENDEKA	1	1	23	25
BENDIBA	12	0	0	12
BENDIKA	11	0	0	11
BENIDIBA	1	0	0	1
BENTECA	0	1	0	1
BERDEKA	0	0	1	1
BINDEBA	1	0	0	1
BINDIKA	1	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Bendeka **Established name:** Bendamustine **Dosage form:** Intravenous Infusion **Strength(s):**100 mg/4 mL (25 mg/mL) **Usual Dose:** 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.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	BENDEKA***	100	Subject of this review
2.	BENDOPA (Phonetic Score: 86) (Orthographic Score: 75)	80	The suffixes of this name pair have sufficient orthographic differences: 'eka' vs 'opa'. The third syllable of this name pair sound different. This product is Withdrawn FR effective 6/25/1993.
3.	BENTEX (Phonetic Score: 76)	72	There is a cross stroke in the infix of Bentex versus the non-cross stroke in the infix of Bendeka. The extra last letter ('a') at the end of Bendeka has sufficient orthographic differences. The Bendeka name contains an extra syllable.
4.	BIDEX-A	71	The third ('n' versus 'd") and fourth letters ('d' versus

	(Orthographic Score: 73)		'e') of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different. No generic equivalents available.
5.	BINACA (Phonetic Score: 71) (Orthographic Score: 70)	70	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. This is an OTC anticavity toothpaste, not a drug.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	BENZAC AC (Phonetic Score: 76)	69
2.	BENZAC W (Phonetic Score: 82)	69
3.	BENZA (Orthographic Score: 71)	64
4.	BENZIQ (Phonetic Score: 79)	63
5.	BENICAR	62
6.	BELBUCA***	60
7.	BENZEPRO	60
8.	PANDEX (Phonetic Score: 73)	60
9.	BENTASIL	59
10.	BENZEFOAM	58
11.	M-END PE (Phonetic Score: 70)	58
12.	5 BENZAGEL	56
13.	BENEMID	56
14.	BENOJECT-50	56

15.	BIDEX	56
16.	M-END WC	56
17.	BENZO-JEL	55
18.	BETAGAN	55
19.	BONIVA	55
20.	BRONTEX	55
21.	(b) (4) ***	54
22.	BEEPEN-VK	54
23.	BENZ-ALL	54
24.	ENDODAN	54
25.	PHENDIET	54
26.	PHENDIET 105	54
27.	BENSAL	53
28.	BENZODENT	53
29.	FERNDEX	53
30.	BANZEL	52
31.	BENZIQ WASH	52
32.	BIDNASE	52
33.	ENDOXAN	52
34.	MANDELAY	52
35.	TYZEKA	52
36.	BANFLEX	51
37.	BENZOIN	51
38.	BALNETAR	50
39.	BELEODAQ	50
40.	BENSAL HP	50
41.	BENZIQ LS	50
42.	BETANATE	50
43.	BICITRA	50
44.	ENDRATE	50
45.	TANDEM	50

46.	Pentasa (Phonetic Score: **76**)	64
47.	Med-JEC-40 (Phonetic Score: **71**)	52
48.	GENTAK (Phonetic Score: **70**)	60

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Bendeka **Established name:** Bendamustine **Dosage form:** Intravenous Infusion **Strength(s):**100 mg/4 mL (25 mg/mL) **Usual Dose:** 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.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	BENZAC (Phonetic Score: 78)	69	The suffixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
2.	PENDEX (Phonetic Score: 76)	66	The extra last letter ('a') at the end of Bendeka has sufficient orthographic differences. In addition, there are differences in dosing between these two products (Days 1 and 2 of either a 21 or 28 day cycle for Bendeka versus 1 tablet every 12 hours for Pendex). The Bendeka name contains an extra syllable.
3.	BENZACOT	62	The infixes and suffixes of this name pair have

	(Phonetic Score: 71)		sufficient orthographic differences. The second syllables of this name pair sound different.
4.	BENLYSTA	61	The infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different
5.	(b) (4) ***	60	The suffixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
6.	DENDRID	59	The suffixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
7.	ENDEP	58	The suffixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
8.	10 BENZAGEL	56	The infixes of this name pair have sufficient orthographic differences. The 10 Benzagel name contains an extra syllable.
9.	BENZAGEL	56	The infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
10.	CANDEX	56	The suffixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
11.	BENZACLIN	55	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
12.	BEDSIDE-CARE	52	The infixes and suffixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different.
13.	BELKIMA	52	The prefixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
14.	BENEFIX	52	The infixes of this name pair have sufficient orthographic differences

			The second and third syllables of this name pair sound different.
15.	NAMENDA	52	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
16.	STENDRA	51	The infixes of this name pair have sufficient orthographic differences. The Bendeka name contains an extra syllable.
17.	ENDACOF C	50	The suffixes of this name pair have sufficient orthographic differences. The Endacof C name contains an extra syllable.
18.	ZENZEDI (Phonetic Score: **71**)	54	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Benadryl	44
2.	Bendamustine	42
3.	Benzyl Alcohol	35
4.	Depakote	41
5.	Ranexa	47

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions

1.	BEN-AQUA	65	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
2.	BENDECTIN	65	This name was identified by the Drugs at FDA database and (b) (4) The Brand is discontinued with no generic equivalent available. NDA 010598 withdrawn FR effective 3/13/2009.
3.	BONJELA (Orthographic Score: 72)	64	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
4.	BEN TANN	60	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
5.	BENERVA	60	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
6.	BENZIE PAK	60	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
7.	BETADEX	60	This name was identified in the RxNorm database.

			However, we were unable to find product characteristics in commonly used drug databases.
8.	BROMDEC (Phonetic Score: 72)	60	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
9.	BENZYL PCA	59	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
10.	BANEX-LA	58	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
11.	BENZENE	57	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
12.	BANCAP	56	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. ANDA 088889 withdrawn FR effective 12/9/92.
13.	BENZOATE	56	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

14.	GENDECON	56	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
15.	(b) (4) ***	55	This name was identified by Name Entered by Safety Evaluator databases. However, this proposed name was withdrawn and not reviewed. NDA (b) (4)
16.	(b) (4) ***	55	This name was identified by Name Entered by Safety Evaluator databases. Proposed proprietary name found unacceptable by DMEPA (b) (4)
17.	ANDEC	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
18.	BANADYNE	54	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
19.	BANCAP HC	54	This name was identified by the RxNorm and Drugs at FDA databases. However, this product is listed as deactivated in

			Redbook with no generic equivalents.
20.	BENEKRAFT/BENEKRAFT 25	54	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
21.	BETAPAR	54	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. NDA 016053 withdrawn FR effective 5/6/1985.
22.	BITEX	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
23.	M-END MAX	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
24.	PHENDACOF	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
25.	RONDEC	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
26.	BEXTRA	53	This name was identified by

			the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. NDA 021341 withdrawn FR effective 8/2/2013 for safety reasons.
27.	BENCORT	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
28.	BENZEPRIL	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
29.	BENZOQUICK	52	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
30.	BETASAL	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
31.	BENZOYL PEROXIDE	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
32.	BALANTA	51	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly

			used drug databases.
33.	ENDACOF AC	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
34.	ENDAFED	51	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
35.	PEN-BEN	51	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
36.	RONDEX	51	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
37.	BENZONATE	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
38.	(b) (4) ***	50	This name was identified in the Name Entered by Safety Evaluator database. However, this is an established name for Onsolis*** found acceptable for IND (b) (4) /NDA 22266. This application status is

			inactive.
39.	BEPADIN	50	This name was identified by the Drugs at FDA database. The Brand is discontinued with no generic equivalent available. NDA 019001 withdrawn FR effective 8/17/2005.
40.	BETA-HC	50	This name was identified by the Drugs at FDA and RxNorm databases. The Brand is discontinued with no generic equivalent available. ANDA 089495 withdrawn FR effective 10/16/2000 .
41.	BETNELAN	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
42.	BI-TANN DP	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
43.	(b) (4) ***	50	The name was identified by the Name Entered By Safety Evaluator database. This proposed proprietary name was withdrawn by the Applicant. A new proprietary name was found acceptable, (b) (4) ***. This application status is withdrawn.
44.	BRONDELATE	50	This name was identified by the RxNorm database.

			However, this product is listed as deactivated in Redbook with no generic equivalents.
45.	DEFEND II	50	This name was identified by the RxNorm database. However, this product is a Veterinary product.
46.	ENDAL CD	50	This name was identified by the RxNorm database. However, this product is listed as discontinued in Facts and Comparison with no generic equivalents.
47.	RENDELLS	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
48.	VENDONE	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook with no generic equivalents.
49.	Pindac (Phonetic Score: **77**)	60	This name was identified by the Drugs at FDA and RxNorm databases. The Brand is discontinued with no generic equivalent available. ANDA 089495 withdrawn FR effective 10/16/2000.
50.	Pee-Vee K (Phonetic Score: **76)**	61	This name was identified in the POCA database. However, we were unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	DEL-BETA	62
2.	PEN-VEE K	61
3.	DEMADEX	60
4.	ENTEX LA	59
5.	VITEKTA	58
6.	DENT-O-KAIN	57
7.	PHENYTEK	57
8.	CHEMDEC	56
9.	DENTI CARE	56
10.	DENTICARE	56
11.	EMBEDA	56
12.	GENEXA	56
13.	GENTEX LA	56
14.	INVEGA	56
15.	KEN-JEC	56
16.	KEN-JEC 40	56
17.	MENTAX	56
18.	PHENTEX LA	56
19.	GENESA	55
20.	AVANDIA	54
21.	CENTEX	54
22.	DANDREX	54
23.	DENTAGEL	54
24.	DIABETA	54
25.	LINJETA	54
26.	MEDA CAP	54

27.	MEDEX-LA	54
28.	MEDIDEX LA	54
29.	PENMET	54
30.	VYNDAQEL	54
31.	ZEBETA	54
32.	DYNABAC	53
33.	MINTEX	53
34.	SANFED A	53
35.	SENATEC	53
36.	ABVANTEC	52
37.	CERDELGA	52
38.	DEMADEX I.V.	52
39.	DE-SONE LA	52
40.	DESPEC	52
41.	DYNEX LA	52
42.	ENTEX	52
43.	MINICA	52
44.	MINITEC	52
45.	PEN VK	52
46.	PENJECT	52
47.	PRENEXA	52
48.	RENVELA	52
49.	SANDRENA	52
50.	SINODEC	52
51.	ZANTAC	52
52.	ZANTAC 150	52
53.	ZANTAC 25	52
54.	ZANTAC 300	52
55.	ZANTAC 75	52
56.	ALBENZA	51
57.	ENZYCAP	51

58.	PEDTE-PAK-4	51
59.	PENLAC	51
60.	PENTETATE	51
61.	SANTEX LA	51
62.	TENCET	51
63.	TIBTIBA	51
64.	VANIQA	51
65.	AN-DTPA	50
66.	CINSENTA	50
67.	DECA	50
68.	DENOREX	50
69.	DENTIPATCH	50
70.	DIGITEK	50
71.	ENTEX S	50
72.	FENEX-LA	50
73.	GANDA	50
74.	GENTACALM	50
75.	JENCYCLA	50
76.	JENLOGA	50
77.	LENVIMA	50
78.	MEDEREK	50
79.	MEDESAL	50
80.	MEDIDEX	50
81.	MENACTRA	50
82.	METACAM	50
83.	MONONESSA	50
84.	ONZETRA	50
85.	PENTACEF	50
86.	PENTACEL	50
87.	PONTEVIA	50
88.	RENITEC	50

89.	RENOTEC	50
90.	TANABID DA	50
91.	TENIVAC	50
92.	VENCLEXTA	50
93.	ZENPEP	50

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/s/

MICHELLE K RUTLEDGE
06/15/2015

YELENA L MASLOV
06/16/2015

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:	April 2, 2015
Application Type and Number:	NDA 208194
Product Name and Strength:	(b) (4) (bendamustine) Injection, 25 mg/mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eagle Pharmaceuticals
Panorama #:	2015-49450
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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/s/

TINGTING N GAO
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CHI-MING TU
04/02/2015