CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212209Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	March 3, 2022
Application Type and Number:	NDA 212209
Product Name and Strength:	Vivimusta (Bendamustine HCl) Injection, 100 mg/4 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Slayback Pharma LLC (Slayback)
PNR ID #:	2022-1044724376
DMEPA 2 Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, FISMP

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Slayback previously submitted the proposed proprietary name, (b) (4) on December 15, 2020 under NDA 212209. However, on March 10, 2021, we found the name, (b) (4) unacceptable due to (b) (4), (b) (4).[a] Slayback then submitted a Name Reconsideration Request for the proposed proprietary name, (b) (4) on April 26, 2021. Upon reconsideration, we found the name, (b) (4) unacceptable July 22, 2021[b] from a safety perspective.

Thus, Slayback submitted the name, Vivimusta, for review on January 10, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 10, 2022.

- Intended Pronunciation: VI-VI-MUS-TAh
- Active Ingredient: Bendamustine HCl
- Indication of Use:
    - Chronic lymphocytic leukemia (CLL). Efficacy relative to first line therapies other than chlorambucil has not been established.
    - Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
- Route of Administration: Intravenous Infusion
- Dosage Form: Injection
- Strength: 100 mg/4 mL (25 mg/mL)
- Dose and Frequency:
    - CLL: 100 mg/m^2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles.

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[a] Straka, M. Proprietary Name Review for (b) (4) (NDA 212209). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 10. Panorama No. 2020-1044336742.

[b] Straka, M. Proprietary Name Reconsideration Review for (b) (4) (NDA 212209). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUL 22. Panorama No. 2021-1044723940.

- NHL: 120 mg/m^2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles

- How Supplied: Injection as a (b) (4) solution in a multiple dose vial.
- Storage: Store refrigerated, 2° to 8°C (36° to 46°F). Retain in original carton until time of use to protect from light.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vivimusta would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Vivimusta, however the Division of Hematologic Malignancies 2 (DHM 2)expressed the following concern:

"We are concerned the "VIVI" part of "VIVIMUSTA" associates the product with "life", "living", or "alive", and may be promotional. "Viv-" comes from Latin (see https://wordinfo.info/unit/2318), and this is passed down to other languages. For example, a Spanish-speaker may associate "VIVIMUSTA" with "vivir", or "to live" (see https://www.spanishdict.com/translate/vivir)."

In response to this concern, OPDP re-evaluated the proposed proprietary name Vivimusta. Upon re-evaluation OPDP stated:

> In light of the Division of Hematologic Malignancies 2's (DHM 2) concern noted in the email below, OPDP has re-evaluated the proposed tradename "Vivimusta." OPDP maintains our non-objection to "Vivimusta" from a promotional perspective. The proposed indication is chronic lymphocytic leukemia. The OPDP PNR team discussed during the initial review whether the proposed name could possibly evoke the word "viv." During this initial review, OPDP noted the intended pronunciation of the proposed proprietary name is "VI-VI-MUS-TAh" (emphasis added) not "viv-i" and would not easily evoke "viv". Therefore, OPDP has determined that the proposed name is not false or misleading from a promotional perspective. We appreciate the feedback from DHM 2 and the opportunity to re-evaluate this proposed tradename, but we respectfully maintain our non-objection. OPDP will closely monitor any future promotional materials for any false or misleading claims related to the concerns raised by DHM 2."

This information was communicated to DHM2 and DHM2 did not forward any additional concerns.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Vivimusta.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Slayback did not provide a derivation or intended meaning for the proposed proprietary name, Vivimusta, in their submission. This proprietary name is comprised of a single word that contains the letters 'iv', which is the abbreviation for the intravenous route of administration. Although we typically discourage the inclusion of medical abbreviations in proprietary names, given that this product is administered intravenously, the location of this abbreviation in the middle of the name, and the lack of prominence of this abbreviation, makes it unlikely that the letters 'iv' within the proposed proprietary name, Vivimusta, could lead to confusion in this case.

2.2.3 Comments from Other Review Disciplines at Initial Review

On February 25, 2022, the Division of Hematologic Malignancies 2 (DHM 2) forwarded a comment/concern relating to Vivimusta at the initial phase of the review (see Section 2.1).

2.2.4 FDA Name Simulation Studies

One Hundred Three (103) practitioners participated in DMEPA's prescription studies for Vivimusta. 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 prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 82 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1

[c] USAN stem search conducted on February 4, 2022.

[d] POCA search conducted on February 4, 2022 in version 4.4.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	76
Low similarity name pair: combined match percentage score ≤54%	5

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

Our analysis of the 82 names contained in Table 1 determined none of the names will pose a risk for confusion with Vivimusta as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On March 3, 2022, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

3 CONCLUSION

The proposed proprietary name, Vivimusta, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO SLAYBACK PHARMA LLC

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

If any of the proposed product characteristics as stated in your submission, received on January 10, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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 DNDP. OPDP or DNDP 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 DNDP 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. [e]

[e] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***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 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 55% 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 ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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) may be limited when the strength or dose overlaps. DMEPA reviews 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

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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 does 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?		

Reference ID: 4949020

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% 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: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • 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.

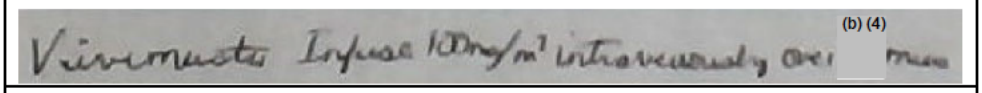
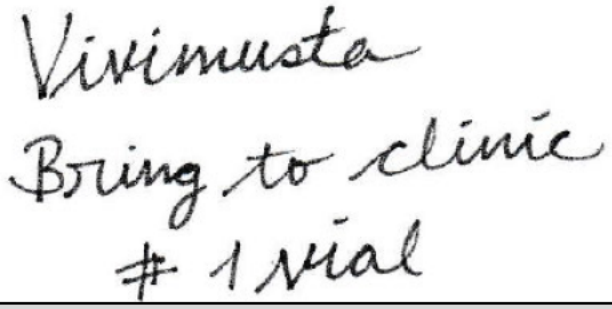
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤54%).

Names with low similarity are generally acceptable 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vivimusta Study (Conducted on February 4, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  (b) (4)	Vivimusta Bring to clinic Dispense #1 vial
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vivimusta	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vivimusta

262 People Received Study

103 People Responded

Study Name: Vivimusta

Total	24	32	23	24	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
VIVA-MASTA	0	0	1	0	1
VIVAMUSTA	0	0	5	0	5
VIVEDMASTO	0	0	1	0	1
VIVEMIST	0	0	0	1	1
VIVEMUSTIN	0	0	0	1	1
VIVEMUSTO	0	0	0	1	1
VIVEMUSTU	0	0	0	2	2
VIVIDMASTA	0	0	2	0	2
VIVIDMUSTA	0	0	1	0	1
VIVIMASTA	0	0	1	0	1
VIVIMASTI	0	0	0	1	1
VIVIMOSTA	0	0	1	0	1
VIVIMUSTA	23	32	8	6	69
VIVIMUSTI	0	0	0	2	2
VIVIMUSTIS INFUSE	0	0	0	1	1
VIVIMUSTO	0	0	0	3	3
VIVIMUSTRO	0	0	0	1	1
VIVIMUSTU	0	0	0	2	2
VIVINMUSTA	0	0	1	0	1

VIVMUSTA	1	0	0	0	1
VIVOMASTA	0	0	1	0	1
VIVUMUSTA	0	0	0	1	1
VIVUMUSTO INFUSE	0	0	0	1	1
VRIVEMUSTIS	0	0	0	1	1
ZIVENMOSCA	0	0	1	0	1

Reference ID: 4949020

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

No.	**Proposed name:** Vivimusta **Established name:** Bendamustine HCl **Dosage form:** Injection **Strength(s):** 100 mg/4 mL (25 mg/mL) **Usual Dose:** • CLL: 100 mg/m2 infused intravenously over (b)(4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. • NHL: 120 mg/m2 infused intravenously over (b)(4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.	**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.	Vivimusta***	100	This name is the subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
	N/A	

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Vivimusta **Established name:** Bendamustine HCl **Dosage form:** Injection **Strength(s):** 100 mg/4 mL (25 mg/mL) **Usual Dose:** • CLL: 100 mg/m2 infused intravenously over (b)(4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. • NHL: 120 mg/m2 infused intravenously over (b)(4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.	**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.	Vagistat	64	This name pair has sufficient orthographic and phonetic differences.
2.	Vagistat-1	64	This name pair has sufficient orthographic and phonetic differences.
3.	Vorinostat	64	Orthographically, the infix (-ivi- vs. -oro-) provides some difference. In addition, Vorinostat has an upstroke letter 't' which is not present in Vivimusta***. Phonetically, the name has sufficient differences ('Vo' vs. 'Vi'), ('rin' vs. 'vi'), ('o' vs. 'mus') and ('stat' vs. 'tah') do not sound similar. In addition, while both products are single strength where the strength may be omitted, the following non-overlapping product characteristics would help to mitigate the error if included on a prescription: dose (400 mg vs. 100-120 mg/m^2), frequency (Daily vs Days 1 and 2 of a 21 or 28 day cycle), route (oral vs. intravenous) and dosage form (capsule vs. injection)

No.	**Proposed name:** Vivimusta **Established name:** Bendamustine HCl **Dosage form:** Injection **Strength(s):** 100 mg/4 mL (25 mg/mL) **Usual Dose:** • CLL: 100 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. • NHL: 120 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.	**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**
4.	Evista	62	This name pair has sufficient orthographic and phonetic differences.
5.	Veramyst	62	This name pair has sufficient orthographic and phonetic differences.
6.	Sinustab	61	This name pair has sufficient orthographic and phonetic differences.
7.	Vitamin A	60	This name pair has sufficient orthographic and phonetic differences.
8.	Vitastem	59	This name pair has sufficient orthographic and phonetic differences.
9.	Tavist	58	This name pair has sufficient orthographic and phonetic differences.
10.	Tavist-1	58	This name pair has sufficient orthographic and phonetic differences.
11.	Verrustat	58	This name pair has sufficient orthographic and phonetic differences.
12.	Vitamin D	58	This name pair has sufficient orthographic and phonetic differences.
13.	Vitamin D3	58	This name pair has sufficient orthographic and phonetic differences.
14.	Vitamin K	58	This name pair has sufficient orthographic and phonetic differences.
15.	Vitamin K 1	58	This name pair has sufficient orthographic and phonetic differences.
16.	Vitamin K 2	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Vivimusta **Established name:** Bendamustine HCl **Dosage form:** Injection **Strength(s):** 100 mg/4 mL (25 mg/mL) **Usual Dose:** • CLL: 100 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. • NHL: 120 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.	**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**
17.	Vitamin K 3	58	This name pair has sufficient orthographic and phonetic differences.
18.	Vitamin K1	58	This name pair has sufficient orthographic and phonetic differences.
19.	Vitamin K2	58	This name pair has sufficient orthographic and phonetic differences.
20.	Vitamin K3	58	This name pair has sufficient orthographic and phonetic differences.
21.	Vitamin K7	58	This name pair has sufficient orthographic and phonetic differences.
22.	Vita-Respa	58	This name pair has sufficient orthographic and phonetic differences.
23.	Viva-Drops	58	This name pair has sufficient orthographic and phonetic differences.
24.	Belinostat	58	This name pair has sufficient orthographic and phonetic differences.
25.	Dymista	58	This name pair has sufficient orthographic and phonetic differences.
26.	Miglustat	58	This name pair has sufficient orthographic and phonetic differences.
27.	Vitamin B 12	57	This name pair has sufficient orthographic and phonetic differences.
28.	Vitamin B12	57	This name pair has sufficient orthographic and phonetic differences.
29.	Vitamin B6	57	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Vivimusta **Established name:** Bendamustine HCl **Dosage form:** Injection **Strength(s):** 100 mg/4 mL (25 mg/mL) **Usual Dose:** • CLL: 100 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. • NHL: 120 mg/m2 infused intravenously over (b) (4) minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.	**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**
30.	Vitamin B9	57	This name pair has sufficient orthographic and phonetic differences.
31.	Vivactil	57	This name pair has sufficient orthographic and phonetic differences.
32.	Zolpimist	57	This name pair has sufficient orthographic and phonetic differences.
33.	Breezee Mist	56	This name pair has sufficient orthographic and phonetic differences.
34.	Vigamox	56	This name pair has sufficient orthographic and phonetic differences.
35.	Vistacot	56	This name pair has sufficient orthographic and phonetic differences.
36.	Vitamin Mk 7	56	This name pair has sufficient orthographic and phonetic differences.
37.	Vitamin Mk7	56	This name pair has sufficient orthographic and phonetic differences.
38.	Derma stat	56	This name pair has sufficient orthographic and phonetic differences.
39.	Vistaject-50	55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Vistra	54

No.	Name	POCA Score (%)
2.	Simvastatin	54
3.	Tavist Sinus	54
4.	Sustiva	52
5.	(b) (4)	52

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.	(b) (4)	64	Proposed proprietary name for NDA 212209 found unacceptable by DMEPA (OSE# 2020-1044336742). NDA 212209 is currently under review with the proposed proprietary name Vivimusta***.
2.	Tavist Da	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Bilivist	62	Discontinued per Drugs@FDA with no generic equivalents available. ANDA 087768 withdrawn FR effective April 26, 1996.
4.	(b) (4)	61	Proposed proprietary name for IND 133661 found unacceptable by DMEPA (OSE# 2020-41635742). Proposed proprietary name Pluvicto*** was found conditionally acceptable under IND 133661 and NDA 215833. .
5.	Visine Extra	60	International product marketed in Mexico. International product formerly marketed in Indonesia.
6.	Bismusal	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Ilomastat	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Racemistat	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	stamoist E	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available
10.	Venastat	56	Product is not a drug. It is an herbal.

No.	Name	POCA Score (%)	Failure preventions
11.	Vicks Vaposteam	56	Product is not a drug. It is an additive for hot steam vaporizers.
12.	Vigam-S	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Abetimus	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Clinistat	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	stamoist La	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	(b) (4)	55	(b) (4) Product approved under NDA 213464 on August 6, 2020 under the proprietary name Lampit.
17.	stamoist	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g].

No.	Name	POCA Score (%)
1.	Evamist	66
2.	Sinumist	64
3.	Pediamist	60
4.	Seba-Moist	60
5.	Avibactam	58
6.	Evovist	58
7.	Gadavist	58
8.	Kesimpta	58
9.	Medipaste	58
10.	Nazo-Mist	58
11.	Pan-Mist La	57
12.	(b) (4)	57

[g] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
13.	Diazemuls	56
14.	M.V.I. Adult	56
15.	M.V.I.-12 Adult	56
16.	(b) (4)	56
17.	Sea Mist	56
18.	Siltuss Das	56
19.	Maxi-Tuss Sa	55
20.	Mekinist	55

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PROPRIETARY NAME RECONSIDERATION 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:	July 22, 2021
Application Type and Number:	NDA 212209
Product Name and Strength:	(b) (4) (bendamustine hydrochloride) injection, 25 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Slayback Pharma LLC (Slayback)
Panorama or PNR ID #:	2021-1044723940
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, FISMP
DMEPA Director (Acting):	Danielle Harris, PharmD

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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)

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Date of This Review:	March 10, 2021
Application Type and Number:	NDA 212209
Product Name and Strength:	(b) (4) (bendamustine hydrochloride) injection, 25 mg/mL
Total Product Strength:	100 mg/4 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Slayback Pharma LLC (Slayback)
Panorama/PNR ID #:	2020-1044336742
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, FISMP

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