CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761104Orig1s000

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:	March 12, 2018
Application Type and Number:	BLA 761104
Product Name and Strength:	Lumoxiti (moxetumomab pasudotox) for injection (b) (4) mg per vial*
Total Product Strength:	(b) (4) mg per vial*
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	AstraZeneca
Panorama #:	2017-19746038
DMEPA Safety Evaluator:	Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader:	Hina Mehta, PharmD

* The product strength is being evaluated by Office of Product Quality (OPQ). For purposes of this proprietary name review, we evaluated the strength as (b) (4) mg per vial.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lumoxiti, 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), for this proposed proprietary name.

1.1 REGULATORY HISTORY

On February 6, 2017, the Applicant submitted the proposed proprietary name (b) (4) under IND 115709, which was found conditionally acceptable (RCM# 2017-13014796) on July 27, 2017[a]. The Applicant submitted the proposed proprietary name Lumoxiti on December 15, 2017, and withdrew the conditionally acceptable proprietary name (b) (4) on December 21, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 15, 2017.

- Intended Pronunciation: loo-MOCKS-eh-tee
- Active Ingredient: moxetumomab pasudotox
- Indication of Use: For the treatment of adult patients with relapsed or refractory hairy cell leukemia.
- Route of Administration: Intravenous infusion
- Dosage Form: for injection (lyophilized powder)
- Strength: (b) (4) mg per vial*
- Dose and Frequency: 0.04 mg/kg on days 1,3,5 of each cycle, up to a maximum of 6 cycles
- How Supplied: Single-dose vials
- Storage: Refrigerate 2°C to 8°C (36°F to 46°F), in original carton to protect from light.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

[a] Rimmel, S. Proprietary Name Review (b) (4) IND 115709 [Acceptable]. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 27 JUL 2017. RCM No.:2017-13014796.

* The product strength is being evaluated by Office of Product Quality (OPQ). For purposes of this proprietary name review, we evaluated the strength as (b) (4) mg per vial.

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Lumoxiti in their submission. 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 12, 2018 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 FDA Name Simulation Studies

Ninety-three (n=93) 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 72 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 with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Lumoxiti will be available in a strength of (b) (4) mg*. Since (b) (4) mg and (b) (4) mg are not typical strengths that are commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap.

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[b] USAN stem search conducted on January 25, 2018.

[c] POCA search conducted on January 17, 2018 in version 4.2.

* The product strength is being evaluated by Office of Product Quality (OPQ). For purposes of this proprietary name review, we evaluated the strength as (b) (4) mg per vial.

Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.1 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	70
Low similarity name pair: combined match percentage score ≤54%	11

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

Our analysis of the 83 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.3 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on March 5, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on March 9, 2018, they stated no additional concerns with the proposed proprietary name, Lumoxiti.

3 CONCLUSION

The proposed proprietary name 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 THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on December 15, 2017, 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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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. [d]

[d] 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 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[e]. 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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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 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?		

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. Lumoxiti Study (Conducted on January 12, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Lumoxiti 1mg inject IV today Outpatient Prescription: Lumoxiti Bring to clinic Dispense # 3 vials	Lumoxiti Bring to clinic. Dispense # 3 vials

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Lumoxiti

As of Date 1/30/2018

293 People Received Study

93 People Responded

Study Name: Lumoxiti

Total	30	29	34	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
FLUMAXATI	0	1	0	1
FLUMAXATY	0	1	0	1
FLUMAXITI	0	1	0	1
FLUMOXETEY	0	1	0	1

FLUMOXETY	0	1	0	1
FLUMOXITI	0	1	0	1
FLUMOXITY	0	1	0	1
HULMOXATEE	0	1	0	1
LOMOXITI	0	0	1	1
LUMOXATEE	0	1	0	1
LUMOXATI	0	3	0	3
LUMOXETI	0	3	0	3
LUMOXITA	0	0	1	1
LUMOXITI	29	3	30	62
LUMOXITIE	0	1	0	1
LUMOXITY	0	9	0	9
LUMOZITI	1	0	0	1
LUMSXITI	0	0	1	1
LUVMOXITI	0	0	1	1
RUMOXATI	0	1	0	1

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

No.	**Proposed name:** Lumoxiti **Established name:** moxetumomab pasudotox **Dosage form:** For injection **Strength(s):** (b) (4) mg per vial* **Usual Dose:** 0.04 mg/kg on days 1, 3, 5 of each cycle, up to a maximum of 6 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.	Lumoxiti	100	Subject of the review
2.	(b) (4) ***	75	(b) (4)

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 (%)
3.	Mexitil	68
4.	Loduxir	64
5.	Loxicom	62
6.	Moxilin	61
7.	Flumist 2015-2016	60
8.	Lomustine	59
9.	Amoxil	58
10.	Flucloxin	58
11.	Loxitane Im	58
12.	Lumacaftor	58
13.	Ferumoxytol	57
14.	Lumason	57
15.	Lumicain	57
16.	Amoxicillin	56
17.	Amoxil Sf	56
18.	Floxin Otic	56
19.	Lidostat	56
20.	Loxitane C	56
21.	Lumizyme	56
22.	Moxatag	56
23.	Prudoxin	56

* The product strength is being evaluated by Office of Product Quality (OPQ). For purposes of this proprietary name review, we evaluated the strength as (b) (4) mg per vial.

No.	Name	POCA Score (%)
24.	Luvox	56
25.	Utimox	54
26.	Imotil	48

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: Lumoxiti Established name: moxetumomab pasudotox Dosage form: Solution Strength(s): (b) (4) mg per vial* Usual Dose: 0.04 mg/kg on days 1, 3, 5 of each cycle, up to a maximum of 6 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
27.	Amoxicot	66	This name pair has sufficient orthographic and phonetic differences.
28.	(b) (4) ***	66	This name pair has sufficient orthographic and phonetic differences.
29.	Lanoxin	65	Orthographic: The suffixes ('in' vs. 'iti') provide some orthographic differences. Phonetic: Lanoxin has 3 syllables; Lumoxiti has 4 syllables. The third/fourth ('in' vs. 'iti') syllables sound different. Product characteristics: Strength: This name is available in 62.5 mcg, 125 mcg, 187.5 mcg, 250 mcg tablets, 0.25 mg/mL, and 0.1 mg/mL, vs. (b) (4) Dosage form: This name is available as tablet and injection, vs. injection only for Lumoxiti.
30.	Minoxidil	64	This name pair has sufficient orthographic and phonetic differences.
31.	Loxitane	63	This name pair has sufficient orthographic and phonetic differences.

* The product strength is being evaluated by Office of Product Quality (OPQ). For purposes of this proprietary name review, we evaluated the strength as (b) (4) mg per vial.

32.	Ronoxidil	63	This name pair has sufficient orthographic and phonetic differences.
33.	Lomocot	62	This name pair has sufficient orthographic and phonetic differences.

34.	Eloxatin	62	Orthographic: This name begins with different letters (E vs. L). Additionally, the prefixes and infixes (‘Elox’ vs. ‘Lumox’) of this name pair has sufficient orthographic differences. Phonetic: This name pair has sufficient phonetic differences.
35.	Lomotil	62	This name pair has sufficient orthographic and phonetic differences.
36.	Luvox Cr	60	This name pair has sufficient orthographic and phonetic differences.
37.	Luxiq	60	This name pair has sufficient orthographic and phonetic differences.
38.	Fluoxetine	60	Orthographic: The length of the names differ by two letters. Fluoxetine has an additional upstroke letter ‘l’ in the prefix and the suffixes (‘tine’ vs. ‘ti’) provide some orthographic differences. Phonetic: The second syllables ‘-ox’ vs. ‘mox’ and the ending sounds of the suffix (‘tine’ vs. ‘ti’) provide some phonetic differences.
39.	Maxitrol	59	This name pair has sufficient orthographic and phonetic differences.
40.	Floxin I.V.	58	This name pair has sufficient orthographic and phonetic differences.
41.	Cefoxitin	58	This name pair has sufficient orthographic and phonetic differences.
42.	Loprox Ts	58	This name pair has sufficient orthographic and phonetic differences.
43.	Tamoxifen	58	This name pair has sufficient orthographic and phonetic differences.
44.	Eltroxin	55	This name pair has sufficient orthographic and phonetic differences.
45.	Lamictal	55	This name pair has sufficient orthographic and phonetic differences.
46.	Ri-mox Plus	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 (%)
47.	Lumigan	53
48.	Lunesta	53
49.	Olumiant	53
50.	Luminal	48
51.	Lupron	34

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
52.	Amoxidin	64	This is an international amoxicillin product formerly marketed in United Kingdom.
53.	Lornoxicam	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
54.	Amoxi-Tabs	60	This is a veterinary amoxicillin product.
55.	Rimoxyn	58	International product formerly marketed United Kingdom
56.	Gliotoxin	58	One of the ingredients in an unapproved homeopathic product
57.	Rimoxallin	57	International product formerly marketed United Kingdom
58.	Alexitol	57	Foreign product available in Malaysia, Thailand, Italy, Hong Kong, Singapore, United Kingdom, Ireland, and South Africa
59.	Amoxi	56	International product marketed in Argentina and Thailand.
60.	Cinoxate	56	This is an ingredient in sunscreen, but not the name of the sunscreen
61.	Moxidectin	56	This is a veterinary anthelmintic product
62.	Ferumoxsil	56	Discontinued product with no available generics
63.	(b) (4)***	56	This name was found unacceptable on 12/20/2016 under IND (b) (4) (RCM # (b) (4)). The Sponsor submitted the proposed proprietary name (b) (4) which was found unacceptable on 09/08/2017 (RCM # (b) (4)). The Applicant has not submitted a new proposed proprietary name.

No.	Name	POCA Score (%)	Failure preventions
64.	Libetist	55	International product marketed in United Kingdom
65.	Plenaxis	55	NDA 021320 was withdrawn FR effective on August 19, 2013 and there are no generic equivalents.
66.	Livostin	55	Discontinued product per Redbook with no available generics
67.	Loroxide	55	Discontinued product per Redbook with no available generics
68.	Lapnexta	54	Unable to find product characteristics in commonly used drug databases
69.	Pulmotil	52	Veterinary product
70.	Pulmolite	50	Discontinued radiopharmaceutical with no available generics per RedBook
71.	Motilium	48	Foreign product available in Europe

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

No.	Name	POCA Score (%)
72.	Clonixin	62
73.	Flunixin	62
74.	Sumaxin	60
75.	Elobixibat***	60
76.	Ilomastat	58
77.	Momexin	58
78.	Moexipril	57
79.	Fluxid	56
80.	Timoptic	56
81.	Cromoptic	56
82.	Timoptic-Xe	55
83.	Uramaxin	55

[f] 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

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
84.	FluoriMax 5000
85.	Myxcin-C
86.	Ravicti
87.	Neutramaxx 5000
88.	Tolnaftate
89.	Scrub solution
90.	Lancome
91.	Blister Balm
92.	Lancome Teint Miracle
93.	Just Right 5000
94.	Sodium Chloride
95.	Cleaning Wipe/Tube
96.	CloSYS
97.	Hongo Killer
98.	Medicated Lip Balm
99.	Premarin
100.	Signifor
101.	Enjuvia
102.	Dentisse
103.	Colgate
104.	Roccos Old School
105.	Dr VITA Premium Vitamin C
106.	Balsalazide Disodium
107.	Bromday
108.	Crest Complete Multi-Benefit
109.	Pelo Baum Hair Revitalizing Conditioner
110.	Holiday Elegance
111.	PRIME PRIMER HYDRATING
112.	Cellpium super anti wrinkle serum
113.	Agave cactus
114.	Eryfotona Actinica Ultralight
115.	Giorgio Armani Maestro
116.	Crampy Belly Rub
117.	AHC Intense Contour Balm
118.	PVP-I Prep Pads foil
119.	Dove DermaSeries
120.	Sanoba

No.	Name
121.	Derma Dr. lab Hydromoist Cover BB
122.	NERD ACNE TREATMENT
123.	SUGAR FREE LEMON MINT HERB THROAT DROPS
124.	Athomer
125.	Thyrogen
126.	Renokin Hair Revitalizing Conditioner
127.	Polynesia Lagoon Water Hydro
128.	Giazo
129.	EcoCare 270
130.	Artistry Essentials Anti-Blemish Acne Treatment
131.	Aquafresh
132.	PsoraCare
133.	Scrub-In Surgical Scrub Brush/Sponge
134.	EASYDEW DAILY DOUBLE HYDRA
135.	Queens Rose Recovery Serum
136.	AHC THE REAL EYE FOR FACE
137.	Beam

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/s/

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03/12/2018

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03/12/2018