CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761297Orig1s000

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:	September 4, 2024
Application Type and Number:	BLA 761297
Product Name, Dosage Form, and Strength:	Unloxcyt (cosibelimab-ipdl) injection, 300 mg/5 mL (60 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Checkpoint Therapeutics, Inc. (Checkpoint)
PNR ID #:	2024-1044725873
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Acting Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Unloxcyt, 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. Checkpoint submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 133920 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Checkpoint previously submitted the proposed proprietary name, Unloxcyt, on March 24, 2022under IND 133920 and on January 3, 2023 under BLA 761297, and we found the name conditionally acceptable on April 3, 2023.[b] However, the application received a complete response letter on December 15, 2023 due to product quality issues.

Thus, Checkpoint submitted the name Unloxcyt, for review on June 28, 2024 as part of the Class 2 Resubmission for BLA 761297.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 28, 2024[c], and the prescribing information received on August 9, 2024[d].

Table 1. Relevant Product Information for Unloxcyt	
Intended pronunciation:	un-LOX-sit
Nonproprietary name:	cosibelimab-ipdl
Indication:	treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation
Dosage Form:	injection
Strength:	300 mg/5 mL (60 mg/mL)
Route of administration:	intravenous

[a] Request for Proprietary Name Review for cosibelimab: Unloxcyt. Conducted by [redacted] (b) (4) 2022 MAR 24. Available from: \\CDSESUB1\EVSPROD\ind133920\0018\m1\us\118-proprietary-names\request-proprietary-name-unloxcyt.pdf.

[b] Mahmoud, S. Proprietary Name Review for Unloxcyt (IND 133920 and BLA 761297). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 APR 3. PNR ID No. 2022-10447245262023 and 2023-1044724919.

[c] Request for Proprietary Name Review for cosibelimab: Unloxcyt. Conducted by [redacted] (b) (4) 2022 MAR 24. Available from: \\CDSESUB1\EVSPROD\ind133920\0018\m1\us\118-proprietary-names\request-proprietary-name-unloxcyt.pdf

[d] Proposed prescribing information for Unloxcyt. Waltham (MA): Checkpoint Therapeutics, Inc.; 2024 AUG 8. Available from: \\CDSESUB1\EVSPROD\bla761297\0028\m1\us\114-labeling\draft\labeling\proposed-resubmission.docx.

Table 1. Relevant Product Information for Unloxcyt	
Dose and frequency:	1,200 mg every three weeks
How Supplied:	a clear to opalescent, colorless to yellow or slightly brown solution supplied as one 300 mg/5 mL (60 mg/mL) single-dose vial in a carton (NDC 83444-301-10).
Storage:	Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze or shake.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Unloxcyt 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 Unloxcyt. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Unloxcyt.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Checkpoint did not provide a derivation or intended meaning for the proposed proprietary name, Unloxcyt, 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 can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Unloxcyt at the initial phase of the review.

[e] USAN stem search conducted on August 9, 2024.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-three (83) practitioners participated in DMEPA's prescription simulation studies for Unloxcyt. 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[f] identified forty-two (42) names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We also evaluated previously identified names taking into account the change in dosage (b) (4) to 1,200 mg every three weeks. Our evaluation has not altered our previous conclusions regarding the acceptability of the proposed proprietary name, Unloxcyt. Therefore, we identified one name not previously analyzed. This name is included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	1
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the one name contained in Table 2 determined none of the names will pose a risk for confusion with Unloxcyt as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On September 4, 2024, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

[f] POCA search conducted on August 5, 2024 in version 5.9.

3 CONCLUSION

The proposed proprietary name, Unloxcyt, is conditionally acceptable.

3.1 COMMENTS TO CHECKPOINT THERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 28, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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.[g]

*Table 3. 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.

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

*Table 3. 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 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, Cerner RxNorm, Purple Book, 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 4-6) 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 4).
- 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[h]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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.

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

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 OPQ 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 Safety Evaluator 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 4. 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 5: 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	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?

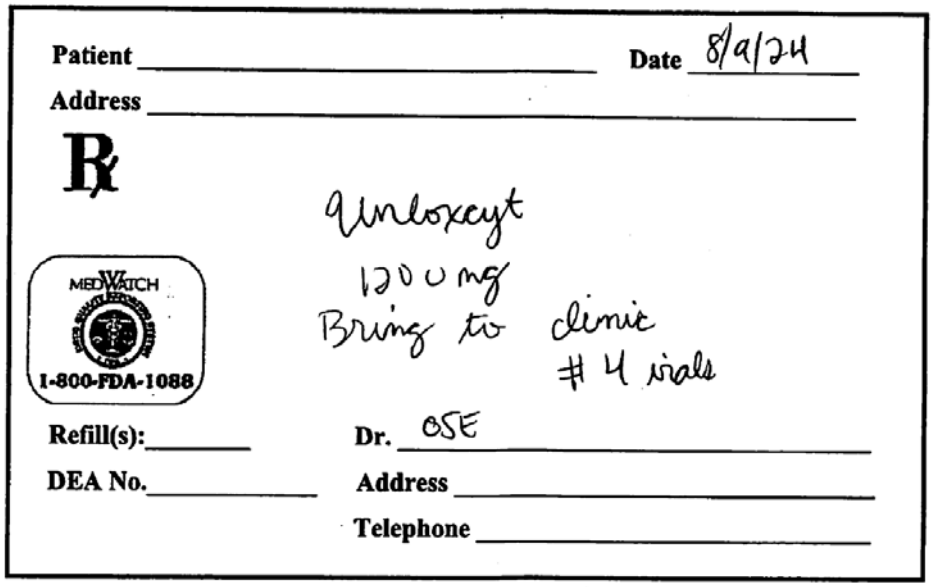
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. 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. Unloxcyt Study (Conducted on 8/9/2024)

<table>
<tr><th>Handwritten Medication Order Prescription</th><th>Verbal Prescription</th></tr>
<tr><td>Medication Order:
 

Outpatient Prescription:
 

</td><td rowspan="3">Unloxcyt
1,200 mg
Bring to clinic.
Dispense 4 vials.</td></tr>
<tr><td>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</td></tr>
<tr><td>Unloxcyt</td></tr>
</table>

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Unloxcyt People Received Study: 192 People Responded: 50					
Total	25	20	14	24	83
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ALOMVIC	0	0	1	0	1
ANLOXET	0	0	1	0	1
ONLOXCIT	0	0	1	0	1
UMLOCKYE	0	0	1	0	1
UMLOXIT	0	0	1	0	1
UNLOCKZIT	0	0	1	0	1
UNLOKSIT	0	0	3	0	3
UNLOXCYT	18	19	0	24	61
UNLOXEYT	5	1	0	0	6
UNLOXIT	0	0	5	0	5

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Unloxcyt Pronunciation: un-LOX-sit Established name: cosibelimab-ipdl Dosage form: injection Strength(s): 300 mg/5 mL (60 mg/mL) Dosage: 1,200 intravenously every three weeks	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.
	N/A		

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: Unloxcyt Pronunciation: un-LOX-sit Established name: cosibelimab-ipdl Dosage form: injection Strength(s): 300 mg/5 mL (60 mg/mL) Dosage: 1,200 intravenously every three weeks	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.	(b) (4) ***	56	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 (%)
	N/A	

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
	N/A		

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

No.	Name	POCA Score (%)
	N/A	

[i] 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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

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SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	8/29/2024
Responsible OND Division:	Division of Oncology 3 (DO3)
Application Type and Number:	BLA 761297
Product Name and Strength:	Unloxcyt (cosibelimab-ipdl) injection 300 mg/5 mL (60 mg/mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Checkpoint Therapeutics, Inc. (Checkpoint)
Nexus NPNS ID #:	2024-259
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -ipdl, for BLA 761297, which was found conditionally acceptable on October 25, 2023[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761297.

1.1 Regulatory History

We found the proposed four-letter suffix, -ipdl, acceptable for BLA 761297 on October 25, 2023[a]. However, BLA 761297 received a Complete Response (CR) letter on December 15, 2023[b]. Thus, Checkpoint submitted a Class 2 Resubmission on June 28, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -ipdl, using the principles described in the applicable guidance[c].

Checkpoint's first proposed suffix, -ipdl, is comprised of 4 distinct letters. We note that the letters 'pd' and 'dl' in the suffix represent the medical abbreviations for 'pediatric dosing' and 'deciliter', respectively. We considered whether the inclusion of the letters 'pd' and 'dl' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -ipdl, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for cosibelimab-ipdl (BLA 761297). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Oct 25. Nexus No.: 2023-165.

[b] Kluetz, P.G. Complete Response (BLA 761297). Silver Spring (MD): FDA, CDER, OND, OOD, DO3 (US); 2023 Dec 15.

[c] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On August 27, 2024, OPDP did not identify any promotional concerns that would render this suffix unacceptable. We acknowledge OPDP's comment that "the suffix 'ipdl' includes 'pdl', which is part of the common acronym for programmed death ligand-1 (PD-L1)". However, DMEPA does not object to proposed suffixes that may connote the mechanism of action of the product. DMEPA 2 also communicated our findings to the Division of Oncology 3 (DO3) on August 29, 2024.

4 CONCLUSION

We find the suffix -ipdl acceptable and recommend the nonproprietary name cosibelimab-ipdl be used throughout the draft labels and labeling.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
08/29/2024 12:38:11 PM

CHI-MING TU
08/29/2024 02:59:04 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	10/25/2023
Responsible OND Division:	select Division
Application Type and Number:	IND 133920 BLA 761297
Product Name and Strength:	Unloxcyt (cosibelimab-ipdl) injection 300 mg/5 mL (60 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Checkpoint Therapeutics, Inc. (Checkpoint)
FDA Received Date:	March 31, 2022 (IND) January 3, 2023 (BLA)
Nexus NPNS ID #:	2022-81 (IND) 2023-165 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Checkpoint for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761297.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On March 31, 2022[a] and January 3, 2023[b], Checkpoint submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product. Table 1 presents a list of suffixes submitted by Checkpoint:

Table 1. Suffixes submitted by Checkpoint***

1.	ipdl
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for Nonproprietary Name Suffix IND 133920. Waltham (MA): Checkpoint Therapeutics, Inc.; 2022 Mar 31. Available from: \\CDSESUB1\EVSPROD\ind133920\0019\m1\us\118-proprietary-names\request-nonproprietary-name-suffix.pdf

[b] Request for Nonproprietary Name Suffix BLA 761297. Waltham (MA):Checkpoint Therapeutics, Inc.; 2023 Jan 03. Available from: \\CDSESUB1\EVSPROD\bla761297\0001\m1\us\118-proprietary-names\request-nonproprietary-name-suffix.pdf

We reviewed Checkpoint's proposed suffixes in the order of preference listed by Checkpoint, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 cosibelimab-ipdl

Checkpoint's first proposed suffix, -ipdl, is comprised of 4 distinct letters. We note that the letters 'pd' and 'dl' in the suffix represent the medical abbreviations for 'pediatric dosing' and 'deciliter', respectively. We considered whether the inclusion of the letters 'pd' and 'dl' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -ipdl, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On October 16, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. We acknowledge OPDP's comment that "the suffix 'ipdl' includes, 'pdl', which is part of the common acronym for programmed death ligand-1 (PD-L1)". However, DMEPA does not object to proposed suffixes that may connote the mechanism of action of the product. DMEPA 2 also communicated our findings to the select Division on October 19, 2023.

4 CONCLUSION

We find Checkpoint's proposed suffix -ipdl acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to cosibelimab-ipdl. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Checkpoint Therapeutics, Inc.

We find the nonproprietary name, cosibelimab-ipdl, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, cosibelimab-ipdl will be the proper name designated in the license. You should revise your proposed labels and labeling

[a] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
10/25/2023 04:42:40 PM

CHI-MING TU
10/25/2023 04:59:37 PM

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 24, 2023
Application Type and Number:	IND 133920 and BLA 761297
Product Name and Strength:	Unloxcyt (cosibelimab-xxxx)[a] injection, 300 mg/5 mL (60 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Checkpoint Therapeutics (Checkpoint)
PNR ID #:	2023-1044724919
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

[a] A nonproprietary name suffix has not been designated for BLA 761297. Therefore, the placeholder '-xxxx' is used throughout this review.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Unloxcyt, 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. Checkpoint submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 24, 2022 under IND 133920 and January 3, 2023 under BLA 761297.[b]

- Intended Pronunciation: un-LOX-sit
- Active Ingredient: cosibelimab-xxxx
- Indication of Use: Cutaneous squamous cell carcinoma.
- Route of Administration: Intravenous infusion
- Dosage Form: injection
- Strength: 300 mg/5 mL (60 mg/mL)
- Dose and Frequency: [redacted] (b) (4) 1,200 mg every three weeks
- How Supplied: One 300 mg/5 mL single-dose vial in a carton.
- Storage: This product should be stored at 2° to 8°C. Protect from light. Do not freeze or shake.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Unloxcyt 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 Unloxcyt. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Unloxcyt.

2.2 SAFETY ASSESSMENT

[b] We note discrepancy between some product characteristics (strength and dose) between the January 3, 2023 proprietary name submission and the proposed labels and labeling that's also submitted in the same supporting document number (SDN 001) on January 3, 2023. For our review, we considered the strength 300 mg/5 mL based on the proposed Prescribing Information (PI) and container labels and carton labeling submitted January 3, 2023. While the proposed PI only states the 1,200 mg dose, we considered [redacted] (b) (4) 1,200 mg stated in the name submission.

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

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

Checkpoint did not provide a derivation or intended meaning for the proposed proprietary name, Unloxcyt, in their submission. This proprietary name is comprised of a single that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 19, 2023, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Unloxcyt at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (n=90) practitioners participated in DMEPA's prescription studies for Unloxcyt.

One participant in the Computerized Prescription Order Entry (CPOE) portion of the study entered an incorrect sequence of letters 'vyy' when searching for the study name. As a result, the CPOE-generated pick list did not contain the proposed study name Unloxcyt as a choice. After 97 seconds passed, the participant then incorrectly selected the name 'Uptravi' as the response, suggesting that this participant selected a random name in order to proceed with the simulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE-based risk. We evaluate the name, Uptravi, in Appendix F.

The remaining 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 41 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, the FDA Name Simulation Studies, and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

[c] USAN stem search conducted on January 6, 2023.

[d] POCA search conducted on January 6, 2023 in version 5.2.

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
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	40
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 46 names contained in Table 1 determined none of the names will pose a risk for confusion with Unloxcyt as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On March 23, 2023, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Unloxcyt, is conditionally acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO CHECKPOINT THERAPEUTICS

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

If any of the proposed product characteristics as stated in your submission, received on January 3, 2023 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?		

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.

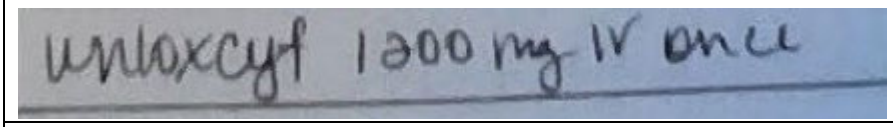
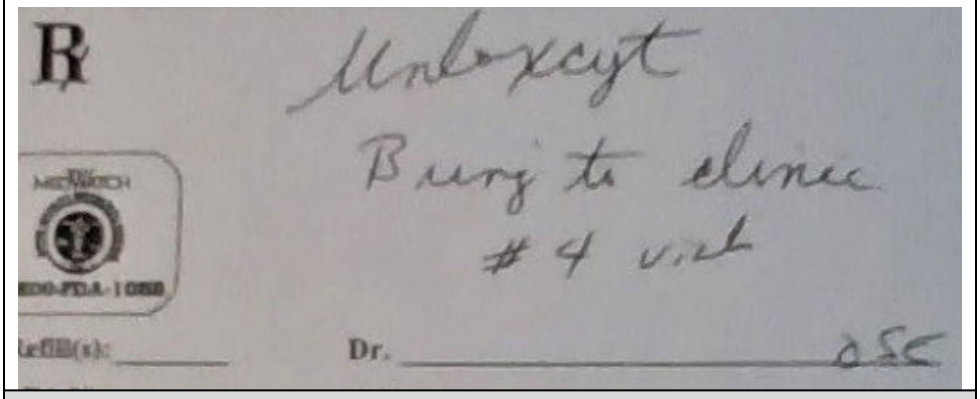
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Unloxcyt Study (Conducted on January 20, 2023)

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

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Unloxcyt
257 People Received
Study
90 People Responded

Study Name: Unloxcyt

Total	21	22	20	27	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
AMLOXID	0	0	1	0	1
AMLOXIT	0	0	1	0	1
ENLOXIT	0	0	1	0	1
FEMLOXIT	0	0	1	0	1
OMLOXIQ	0	0	1	0	1
OMLOXIT	0	0	1	0	1
UMLOXIC	0	0	1	0	1
UMLOXIT	0	0	5	0	5
UNBOXCYT	0	0	0	1	1
UNBXCYT	0	0	0	2	2
UNLAXCYT	0	0	0	1	1
UNLAXIT	0	0	1	0	1
UNLOCKSIT	0	0	2	0	2
UNLOXCYF	16	0	0	0	16
UNLOXCYL	3	0	0	0	3
UNLOXCYT	2	21	0	23	46
UNLOXIT	0	0	5	0	5
UPTRAVI	0	1	0	0	1

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

No.	**Proposed name:** Unloxcyt **Established name:** cosibelimab-xxxx **Dosage form:** injection **Strength(s):** 300 mg/5 mL (60 mg/mL) **Usual Dose:** (b) (4) 1,200 mg intravenous infusion every three weeks	**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.	Unloxcyt	100	Proprietary name 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 (%)
1.	Blincyto	60
2.	Amlactin	58
3.	Naloxone	58
4.	Adlyxin	56
5.	Puroxcin	56
6.	Endocet	56

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:** Unloxcyt **Established name:** cosibelimab-xxxx **Dosage form:** injection **Strength(s):** 300 mg/5 mL (60 mg/mL) **Usual Dose:** (b) (4) 1,200 mg intravenous infusion every three weeks	**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.	Nalex Ac	62	This name pair has sufficient orthographic and phonetic differences.
2.	Eloctate	58	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Unloxcyt **Established name:** cosibelimab-xxxx **Dosage form:** injection **Strength(s):** 300 mg/5 mL (60 mg/mL) **Usual Dose:** (b) (4) 1,200 mg intravenous infusion every three weeks	**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.	Floxin	57	This name pair has sufficient orthographic and phonetic differences.
5.	Uni-Otic	56	This name pair has sufficient orthographic and phonetic differences.
6.	Ciloxan	56	This name pair has sufficient orthographic and phonetic differences.
7.	Condylox	56	This name pair has sufficient orthographic and phonetic differences.
8.	Eloxatin	56	This name pair has sufficient orthographic and phonetic differences.
9.	Eulexin	56	This name pair has sufficient orthographic and phonetic differences.
10.	Paloxin	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.	Ultracet	53
2.	Oxycontin	49
3.	Uroxatral	48
4.	Unasyn	44
5.	Uptravi	26

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.	U-Lactin	60	International product marketed in Israel.
2.	Alloxate	60	Product is a veterinary drug.
3.	Unilax	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
4.	Efloxate	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Flucloxin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Alloxan	56	Product is not a drug. It is a toxic pyrimidone compound.
7.	Amiloxate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	loxicom	56	Product is a veterinary drug.
9.	Endoxan	56	International product marketed in Australia, Belgium and many other countries.
10.	Choloxin	55	Product is deactivated with no generic equivalents available.
11.	Androxy	55	Product is deactivated with no generic equivalents 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.	Nalocet	64
2.	Nulecit	60
3.	Lumoxiti	58
4.	Cinoxate	56
5.	Ilotycin	56
6.	Nalacet	56
7.	Noroxin	56
8.	Sulsoxin	56
9.	Troxyca	56
10.	Lanoxin	55
11.	Sulfoxyl	55
12.	Tolectin	55
13.	Tolectin 600	55

[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

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