CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761400Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	April 10, 2025
Responsible OND Division:	Division of Hematologic Malignancies 2 (DHM2)
Application Type and Number:	BLA 761400
Product Name and Strength:	Lynozyfic (linvoseltamab-gcpt) injection 5 mg/2.5 mL (2 mg/mL and 200 mg/10 mL (20 mg/mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
FDA Received Date:	January 10, 2025
Nexus NPNS ID #:	2025-304
DMEPA 2 Biologics Suffix Specialist:	Carlos Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 Purpose of Review

This review is to reassess our evaluation of the four-letter suffix –gcpt for BLA 761400, which was found conditionally acceptable on July 24, 2024,[a] for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761400.

2 Regulatory History

DMEPA 2 found the proposed nonproprietary name suffix -(b) (4) conditionally acceptable on June 5, 2024.[b] However, on June 24, 2024, Regeneron withdrew the proposed suffix (b) (4) Regeneron requested that the Agency continue review of their proposed suffixes.

The proposed suffix -gcpt was found conditionally acceptable for BLA 761400 on July 24, 2024.[a] However, BLA 761400 received a Complete Response (CR) letter on 8/20/2024.[c] Thus, Regeneron submitted a Class 2 Resubmission on January 10, 2025.

3 Assessment of the Nonproprietary Name

We reassessed the previously conditionally acceptable suffix -gcpt, using the principles described in the Nonproprietary Naming of Biological Products guidance.[d]

We determined that the proposed suffix -gcpt, is not too similar to any other product's 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 lead be misinterpreted, and does not make misrepresentations with respect to safety and efficacy of the product.

4 Communication of DMEPA 2 Analysis

These findings were shared with OPDP. On April 9, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Hematologic Malignancies 2 (DHM2) on April 10, 2025.

5 Conclusion

We find the suffix –gcpt acceptable and recommend the nonproprietary name linvoseltamab-gcpt be used throughout the draft labels and labeling.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for linvoseltamab-gcpt (BLA 761400). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Jul 24. Nexus ID.: 2024-252.
[b] Mena-Grillasca, C. Nonproprietary Name Suffix Review for linvoseltamab-(b) (4) (BLA 761400). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Jun 05. Nexus ID.: 2023-223.
[c] Theoret, M. Complete Response (BLA 761400). Silver Spring (MD): FDA, CDER, OND, Office of Oncologic Diseases (US); 2024 Aug 20.
[d] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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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
04/10/2025 07:15:04 AM

CHI-MING TU
04/10/2025 11:28:01 AM

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)

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Date of This Review:	April 3, 2025
Application Type and Number:	BLA 761400
Product Name, Dosage Form, and Strength:	Lynozyfic (linvoseltamab-xxxx)[a] Injection, 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
PNR ID #:	2025-1044726223
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder linvoseltamab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lynozyfic, 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. Regeneron previously submitted an external name study, conducted by (b) (4) which was reviewed under BLA 761400 (see Section 1.1, below). Regeneron submitted an updated external name study, conducted by (b) (4) during this review cycle.

1.1 REGULATORY HISTORY

Regeneron previously submitted the proposed proprietary name, Lynozyfic, under BLA 761400 on December 22, 2023, and we found the name conditionally acceptable on March 21, 2024.[d] However, BLA 761400 received a Complete Response letter on August 20, 2024 due to facility deficiencies.[e]

Thus, Regeneron submitted the proposed proprietary name, Lynozyfic, for review on January 10, 2025 under BLA 761400 as part of their Class 2 resubmission.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 10, 2025[f] and the prescribing information received on February 7, 2025.[g]

Table 1. Relevant Product Information for Lynozyfic	
Intended Pronunciation:	li noe' zi fik
Nonproprietary Name:	linvoseltamab
Indication:	For the treatment of adult patients (b) (4)

[b] Proprietary Name Safety Summary for LYNOZYFIC. (b) (4) 2023 NOV 01. Available from: \\CDSESUB1\EVSPROD\bla761400\0001\m1\us\118-proprietary-names\propr-names-cro.pdf
[c] Proprietary Name Safety Summary for LYNOZYFIC. (b) (4) 2024 OCT 31. Available from: \\CDSESUB1\EVSPROD\bla761400\0051\m1\us\118-proprietary-names\appendix-1.pdf .
[d] Kundreskas, J. Proprietary Name Review for Lynozyfic (BLA 761400). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 MAR 21. PNR ID No. 2024-1044725549.
[e] Wall, L. Complete Response for REGN5458. Silver Spring (MD): FDA, CDER, OOD (US); 2024 AUG 20. BLA 761400. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af80762bd7
[f] Request for Proprietary Name Review for LYNOZYFIC (BLA 761400). Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2025 JAN 10. Available from: \\CDSESUB1\EVSPROD\bla761400\0051\m1\us\118-proprietary-names\popr-names.pdf.
[g] Proposed prescribing information for Lynozyfic. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2025 FEB 07. Available from: \\CDSESUB1\EVSPROD\bla761400\0055\m1\us\114-labeling\draft\labeling\proposed-uspi.pdf.

<table>
<tr><th colspan="2">Table 1. Relevant Product Information for Lynozyfic</th></tr>
<tr><td>Dosage Form:</td><td>Injection</td></tr>
<tr><td>Strength:</td><td>5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)</td></tr>
<tr><td>Route of Administration:</td><td>Intravenous Infusion</td></tr>
<tr><td>Dose and Frequency:</td><td>The recommended dosage of LYNOZYFIC is step-up doses of 5 mg, 25 mg, and 200 mg, followed by 200 mg weekly for 10 doses, followed by 200 mg biweekly (every 2 weeks).
In patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg, decrease the dosing frequency to 200 mg every 4 weeks.
<table>
<tr><th>Dosing Schedule</th><th>Day</th><th colspan="2">Dose of LYNOZYFIC</th></tr>
<tr><td rowspan="3">Step-Up Dosing Schedule</td><td>Day 1</td><td>Step-up dose 1</td><td>5 mg</td></tr>
<tr><td>Day 8</td><td>Step-up dose 2</td><td>25 mg</td></tr>
<tr><td>Day 15</td><td>First treatment dose</td><td>200 mg</td></tr>
<tr><td>Weekly Dosing Schedule</td><td>One week after Day 15
treatment dose and once weekly from Week 4 to Week 13 for 10 treatment doses</td><td>Second and subsequent treatment doses</td><td>200 mg</td></tr>
<tr><td>Biweekly (Every 2 Weeks) Dosing Schedule</td><td>Week 14 and every 2 weeks thereafter</td><td>Subsequent treatment doses</td><td>200 mg</td></tr>
<tr><td colspan="4">Patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg</td></tr>
<tr><td>Every 4 Weeks Dosing Schedule</td><td>At Week 24 or after and every 4 weeks thereafter</td><td>Subsequent treatment doses</td><td>200 mg</td></tr>
</table>
Dose adjustments for adverse effects: Dose may be resumed at 2.5 mg if the last dose administered was 5 mg.</td></tr>
<tr><td>How Supplied:</td><td>LYNOZYFIC (linvoseltamab-xxxx) injection is a clear to slightly opalescent, colorless to pale yellow solution in a single-dose vial. It is supplied in cartons of:
• One 5 mg/2.5 mL (2 mg/mL) single-dose vial
• One 200 mg/10 mL (20 mg/mL) single-dose vial</td></tr>
<tr><td>Storage:</td><td>Store unopened vial in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake.</td></tr>
</table>

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Lynozyfic 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 Lynozyfic. The Division of Hematologic Malignancies 2 (DHM 2) concurred with the findings of OPDP's assessment for Lynozyfic.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Regeneron did not provide a derivation or intended meaning for the proposed proprietary name, Lynozyfic, in their submission. This proprietary name is comprised of a single word that contains the letter string "YF" which is a medical abbreviation for yellow fever vaccine. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note that the location of the letter string "YF" within the infix of the proposed name means it is unlikely to be separated from the surrounding letters or to be misinterpreted within the context of a prescription and lead to confusion. Therefore, in this case, we do not object to the proposed proprietary name based on the inclusion of this medical abbreviation. Lynozyfic does not contain any other 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 Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Lynozyfic at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-five (95) practitioners participated in DMEPA's prescription simulation studies for Lynozyfic. 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.

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[h] USAN stem search conducted on February 26, 2025.

Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[i] identified 36 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 note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 1 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 and (b) (4) (b) (4) external study. 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%	1

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

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

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 3, 2025, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

3 CONCLUSION

The proposed proprietary name, Lynozyfic, is conditionally acceptable.

[i] POCA search conducted on February 26, 2025 in version 5.9.

3.1 COMMENTS TO REGENERON PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 10, 2025, 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.[j]

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.

[j] 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 (Tables 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 that 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[k]. 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 and 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-

[k] 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

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 as 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?		

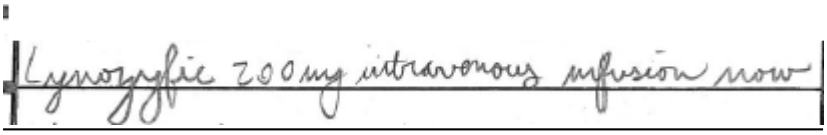
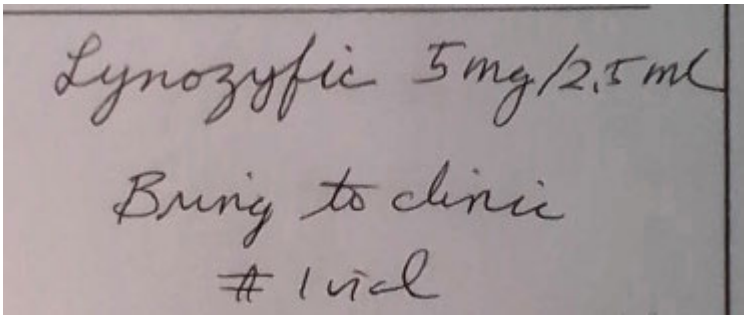
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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 as vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names 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. Lynozyfic Study (Conducted on 3/7/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Lynozyfic 5 mg/2.5 mL Bring to Clinic Dispense 1 vial
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Lynozyfic	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Lynozyfic People Received Study: 167 People Responded: 95					
Total	27	24	18	26	95
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
LINOZIFIC	0	0	1	0	1
LINOZIFYK	0	0	1	0	1
LINOZIPHIC	0	0	1	0	1
LINOZIPIC	0	0	1	0	1
LINOZITHECH	0	0	1	0	1
LINOZYFIC	0	0	3	0	3
LINOZYFIK	0	0	2	0	2
LINOZYFIQ	0	0	1	0	1
LINOZYPHIC	0	0	1	0	1
LINOZYSIC	0	0	1	0	1
LINOZYTEC	0	0	1	0	1
LINOZYZIC	0	0	1	0	1
LYNOGYFIC	1	0	0	0	1
LYNOYYFIC	2	0	0	0	2
LYNOYYFIE	1	0	0	0	1
LYNOZYFIC	17	21	2	26	66
LYNOZYFIE	2	0	0	0	2
LYNOZYFLIC	0	1	0	0	1
LYNOZYLFIC	1	1	0	0	2
LYNOZYLIC	1	1	0	0	2
LYNOZYNYLIC	1	0	0	0	1
LYNOZYPHIQUE	0	0	1	0	1
LYNVOZYFIE	1	0	0	0	1

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

No.	Proposed name: Lynozyfic Pronunciation: li noe' zi fik Established name: linvoseltamab Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Dosage: 2.5 mg, 5 mg, 25 mg, or 200 mg weekly, every 2 weeks, or every 4 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.	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 (%)
1.	(b) (4) ***	60

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: Lynozyfic Pronunciation: li noe' zi fik Established name: linvoseltamab Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Dosage: 2.5 mg, 5 mg, 25 mg, or 200 mg weekly, every 2 weeks, or every 4 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.	N/A		

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

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

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.	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 (%)
1.	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

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/s/

JODY K KUNDRESKAS
04/03/2025 01:30:33 PM

NICOLE F IVERSON
04/03/2025 04:25:12 PM

HINA S MEHTA
04/07/2025 04:20:06 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:	7/24/2024
Responsible OND Division:	Division of Hematologic Malignancies 2 (DHM 2)
Application Type and Number:	BLA 761400
Product Name and Strength:	Lynozyfic (linvoseltamab- gcpt) injection 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
FDA Received Date:	June 24, 2024
Nexus NPNS ID #:	2024-252
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 summarizes our evaluation of the four-letter suffixes proposed by Regeneron for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761400.

2 REGULATORY HISTORY

DMEPA 2 found the proposed nonproprietary name suffix (b) (4) conditionally acceptable on June 5, 2024[a]. However, on June 24, 2024, Regeneron withdrew the proposed suffix (b) (4) (b) (4) Regeneron requested that the Agency continue review of their proposed suffixes.

3 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 24, 2024, Regeneron submitted a list of 6 suffixes, in their order of preference, to be used in the nonproprietary name of their product[b]. Table 1 presents a list of suffixes submitted by Regeneron.

Table 1. Suffixes submitted by Regeneron***

1.	(b) (4)
2.	
3.	
4.	gcpt
5.	(b) (4)
6.	

[a] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761400. Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Jun 05.

[b] Cover Letter. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2024 Jun 24. Available from: \\CDSESUB1\EVSPROD\bla761400\0043\m1\us\12-cover-letters\cover.pdf

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

3.1 linvoseltamab-(b) (4)

Regeneron's first proposed suffix, (b) (4)

We note that the suffix (b) (4) connotes (b) (4) Therefore, we find the proposed suffix (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

3.2 linvoseltamab-(b) (4)

Regeneron's second proposed suffix, (b) (4)

The proposed suffix, (b) (4) has (b) (4) (b) (4) (b) (4) Thus, we find the proposed suffix (b) (4) is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

3.3 linvoseltamab-(b) (4)

Regeneron's third proposed suffix, (b) (4) (b) (4) is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance that states "the proposed suffix should be four letters of which at least three are distinct".

3.4 linvoseltamab-gcpt

Regeneron's fourth proposed suffix, -gcpt, is comprised of 4 distinct letters.

We determined that the proposed suffix - gcpt, 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

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

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.

4 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On July 24, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) on July 24, 2024.

5 CONCLUSION

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

5.1 Recommendations for Regeneron Pharmaceuticals, Inc.

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

We also note that the first three proposed suffixes are unacceptable for the following reasons:

1. linvoseltamab-(b) (4)

   The proposed suffix (b) (4) Therefore, we find the proposed suffix, (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

2. linvoseltamab-(b) (4)

   The proposed suffix, (b) (4) (b) (4)

[redacted] Thus, we find the proposed suffix [redacted] is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

3. linvoseltamab-[redacted]

The proposed suffix, [redacted] is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance that states “the proposed suffix should be four lower case letters of which at least three are distinct”.

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
07/24/2024 04:19:22 PM

DANIELLE M HARRIS on behalf of CHI-MING TU
07/24/2024 04:29:36 PM
Signed on behalf of Chi-Ming Tu

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)

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Date of This Review:	6/5/2024
Responsible OND Division:	select Division
Application Type and Number:	BLA 761400
Product Name and Strength:	Lynozyfic (linvoseltamab-(b) (4)) injection 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
FDA Received Date:	December 22, 2023
Nexus NPNS ID #:	2023-223
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 summarizes our evaluation of the four-letter suffixes proposed by Regeneron for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761400.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On December 22, 2023, Regeneron submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by Regeneron:

Table 1. Suffixes submitted by Regeneron***

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

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

[a] Request for Advice – Four Letter Suffix Submission. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2023 Dec 22. Available from: \\CDSESUB1\EVSPROD\bla761400\0001\m1\us\112-other-correspondence\req-comm.pdf

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

2.1 linvoseltamab-(b) (4)

Regeneron's first proposed suffix, (b) (4).

We note that the suffix (b) (4) Therefore, we find the proposed suffix (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

2.2 linvoseltamab-(b) (4)

Regeneron's second proposed suffix, (b) (4)

We note (b) (4) (b) (4) (b) (4) the proposed proprietary name "Lynozyfic" submitted by the applicant. Thus, we find the proposed suffix (b) (4) is not devoid of meaning as it (b) (4) and is therefore inconsistent with the principle described in the Nonproprietary Naming of Biological Products guidance.

2.3 linvoseltamab-(b) (4)

Regeneron's third proposed suffix, (b) (4) (b) (4)

However, we note that the suffix (b) (4) Therefore, we find the proposed suffix (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

2.4 linvoseltamab-(b) (4)

Regeneron's fourth proposed suffix, (b) (4), is comprised of 4 distinct letters.

We determined that the proposed suffix (b) (4) 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 June 5, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the select Division on June 5, 2024.

4 CONCLUSION

We find Regeneron's proposed suffix [redacted] acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to linvoseltamab-[redacted] DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Regeneron Pharmaceuticals, Inc.

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

We also note that the first three proposed suffixes are unacceptable for the following reasons:

1. linvoseltamab-[redacted]

   The proposed suffix [redacted] Therefore, we find the proposed suffix, [redacted] is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

2. linvoseltamab-[redacted]

   [redacted] Thus, we find the proposed suffix [redacted] is not devoid of meaning as it [redacted] is therefore inconsistent with the principle described in the Nonproprietary Naming of Biological Products guidance.

3. linvoseltamab-(b) (4)

The proposed suffix (b) (4) Therefore, we find the proposed suffix, (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance.

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/s/

CARLOS M MENA-GRILLASCA
06/05/2024 03:11:24 PM

CHI-MING TU
06/05/2024 03:27:33 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 21, 2024
Application Type and Number:	BLA 761400
Product Name, Dosage Form, and Strength:	Lynozyfic (linvoseltamab-xxxx)[a] Injection, 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc (Regeneron)
PNR ID #:	2024-1044725549
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader (Acting):	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature & Labeling:	Hina Mehta, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder linvoseltamab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lynozyfic, 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. Regeneron 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 and the prescribing information received on December 22, 2023[c,d].

Table 1. Relevant Product Information for Lynozyfic	
Intended pronunciation:	li noe' zi fik
Nonproprietary name:	linvoseltamab-xxxx
Indication:	For the treatment of adults with relapsed or refractory multiple myeloma [redacted] (b) (4)
Dosage Form:	Injection
Strength:	5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL)
Route of administration:	Intravenous Infusion

[b] Proprietary Name Safety Summary for Lynozyfic. [redacted] (b) (4) 2023 NOV 01. Available from: \\CDSESUB1\EVSPROD\bla761400\0001\m1\us\118-proprietary-names\propr-names-cro.pdf.

[c] Request for Proprietary Name Review. Wilmington (DE): Regeneron Pharmaceuticals, Inc; 2023 DEC 22. Available from: \\CDSESUB1\EVSPROD\bla761400\0001\m1\us\118-proprietary-names\propr-names-regn.pdf.

[d] Proposed prescribing information for Lynozyfic. Wilmington (DE): Regeneron Pharmaceuticals, Inc; 2023 DEC 22. Available from: \\CDSESUB1\EVSPROD\bla761400\0001\m1\us\114-labeling\draft\labeling\proposed-uspi.pdf.

Table 1. Relevant Product Information for Lynozyfic	
Usual dosage and frequency:	(b) (4) Dose adjustments for adverse effects: Dose may be resumed at 2.5 mg if the last dose administered was 5 mg.
How Supplied:	LYNOZYFIC (linvoseltamab-xxxx) injection is a clear to slightly opalescent, colorless to pale yellow solution (b) (4) (b) (4)
Storage:	Store unopened vial in a refrigerator at 2°C to 8°C (36°F to 46°F) in the 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, Lynozyfic.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Lynozyfic 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 Lynozyfic. The Division of Hematologic Malignancies 2 (DHM 2) concurred with the findings of OPDP's assessment for Lynozyfic.

2.2 SAFETY ASSESSMENT

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

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

Regeneron did not provide a derivation or intended meaning for the proposed proprietary name, Lynozyfic, in their submission. This proprietary name is comprised of a single word that contains the letter string "YF" which is a medical abbreviation for yellow fever vaccine. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note that the location of the letter string "YF" within the infix of the proposed name means it is unlikely to be separated from the surrounding letters or to be misinterpreted within the context of a prescription and lead to confusion. Therefore, in this case, we do not object to the proposed proprietary name based on the inclusion of this medical abbreviation. Lynozyfic does not contain any other 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 February 1, 2024, the Division of Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Lynozyfic at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Sixty-nine practitioners participated in DMEPA's prescription studies for Lynozyfic.

One participant in the Computerized Physician Order Entry (CPOE) study incorrectly selected the name Lynparza. We considered whether additional product characteristics would help differentiate the products during an electronic prescribing scenario.

We note the dosage form (injection vs. tablet), route (intravenous infusion vs. oral), strength (5 mg/2.5 mL (2 mg/mL) or 200 mg/10 mL (20 mg/mL) vs. 100 mg and 150 mg), and frequency (every week, every 2 weeks, or every 4 weeks vs. twice daily) differ between the two products which are unlikely to be overlooked in an electronic prescribing scenario. Additionally, Lynozyfic is an injectable oncologic drug proposed for the treatment of adults with relapsed or refractory multiple myeloma (b) (4)

Because injectable oncologic drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the differences in product characteristics is minimized.

[e] USAN stem search conducted on January 18, 2024.

Orthographically, the suffixes (zyfic vs. parza) of the name pair differ. Phonetically, Lynozyfic has 4 syllables whereas Lynparza has 3 syllables and the second (-noe- vs -par-) and third syllables (-zi- vs. -za) sound different.

When all of the aforementioned factors are considered in totality, we find the risk of name confusion between the name pair is adequately minimized in this case (see Appendix E).

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[f] identified 36 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 lists the number of names retrieved from our POCA search, FDA Prescription Simulation Study, and (b) (4) external study. 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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	35
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 38 names contained in Table 2 determined none of the names will pose a risk for confusion with Lynozyfic as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 21, 2024, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

[f] POCA search conducted on January 18, 2024 in version 5.5.

3 CONCLUSION

The proposed proprietary name, Lynozyfic, is conditionally acceptable.

If you have further questions or need clarifications, please contact Candido Alicea, OSE project manager, at 240-402-8310.

3.1 COMMENTS TO REGENERON PHARMACEUTICALS, INC

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

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?		

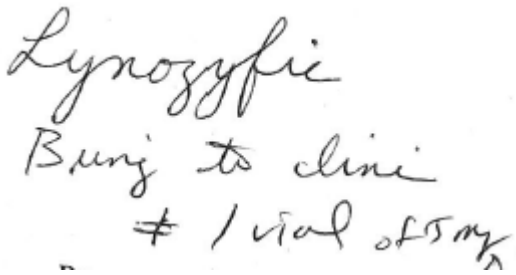
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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. Lynozyfic Study (Conducted on 1/9/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Lynozyfic Bring to Clinic Dispense 1 vial of 5 mg
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Lynozyfic	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Lynozyfic People Received Study: 165 People Responded: 69					
Total	15	20	15	19	69
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
LINOXIFIC	0	0	1	0	1
LINOZIFIC	0	0	2	0	2
LINOZIPHIC	0	0	1	0	1
LINOZYFIC	0	0	1	0	1
LINOZYFIK	0	0	2	0	2
LINOZYPHIC	0	0	1	0	1
LINOZYSIC	0	0	1	0	1
LINOZYTHIC	0	0	1	0	1
LYNOYFIC	1	0	0	0	1
LYNOZIPHIC	0	0	1	0	1
LYNOZITHIC	0	0	1	0	1
LYNOZYFIC	13	13	0	18	44

LYNOZYFIE	1	4	0	0	5
LYNOZYFRI	0	2	0	0	2
LYNOZYPHIC	0	0	2	0	2
LYNOZZFRI	0	1	0	0	1
LYNPARZA	0	0	0	1	1
LYOZYVIC	0	0	1	0	1

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

No.	Proposed name: Lynozyfic Established name: linvoseltamab-xxxx Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Usual dose: 2.5 mg, 5 mg, 25 mg, or 200 mg	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.	Lynozyfic	100	This name is the subject of this review.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4) ***	64
2.	Synovacin	60
3.	(b) (4) ***	56
4.	Leniolisib	56
5.	(b) (4) ***	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: Lynozyfic Established name: linvoseltamab-xxxx Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Usual dose: 2.5 mg, 5 mg, 25 mg, or 200 mg	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.	Lincomycin	64	This name pair has sufficient orthographic differences.
2.	Lanophyllin	60	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Lynozyfic Established name: linvoseltamab-xxxx Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Usual dose: 2.5 mg, 5 mg, 25 mg, or 200 mg	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
3.	Linezolid	60	This name pair has sufficient orthographic differences. Phonetically, the third (zi vs. zoh) and fourth (fik vs. lid) sound different. This name pair differ in frequency (every week, every 2 weeks, or every 4 weeks vs. every 8 to 12 hours). Additionally, Lynozyfic is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals are not communicated by verbal order and typically undergo independent double checks by two pharmacists in the usual clinical setting. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
4.	Lincomycin Hcl	58	This name pair has sufficient orthographic and phonetic differences.
5.	Lincocin	57	This name pair has sufficient orthographic and phonetic differences.
6.	Palynziq	56	This name pair has sufficient orthographic and phonetic differences.
7.	Lanoxin	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Lynozyfic Established name: linvoseltamab-xxxx Dosage form: Injection Strength(s): 5 mg/2.5 mL (2 mg/mL) and 200 mg/10 mL (20 mg/mL) Usual dose: 2.5 mg, 5 mg, 25 mg, or 200 mg	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
8.	Lanolin Acid	55	This name pair has sufficient orthographic and phonetic differences.
9.	Lynparza	46	See FMEA in Section 2.2.4.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Linzess	48

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.	Lanabiotic	60	Brand discontinued with no generic equivalents available. NDA 050598 withdrawn FR effective 06/25/1993.
2.	Lonazolac	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Polynoxylin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Lanozin	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Linco-Jec	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Synotic	58	Veterinary product.
7.	Synovex C	58	Veterinary product.
8.	Lynox	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
9.	Lysozyme	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	(b) (4) ***	56	Proposed proprietary name for CBER IND (b) (4) found unacceptable (b) (4) Entire application withdrawn by the Applicant (b) (4)
11.	Lincobac	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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 (%)
1.	Zinotic Es	58
2.	Clinolipid	58
3.	Clinolipid 20%	58
4.	Zonulysin	57
5.	Salinomycin	56
6.	Galenomycin	56
7.	Synanthic	56
8.	Synvisc	56
9.	Zinotic	55
10.	Glycylic	55
11.	Kinlytic	55

[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

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