

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761152Orig1s000

PROPRIETARY NAME REVIEWS

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:	June 9, 2025
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761152
Product Name and Strength:	Yartemla (narsoplimab-wuug) injection 370 mg/2 mL (185 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Omeros Corporation (Omeros)
FDA Received Date:	March 26, 2025
Nexus NPNS ID #:	2025-321
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 –wuug for BLA 761152, which was found conditionally acceptable on May 6, 2021,^a for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761152.

2 Regulatory History

The proposed suffix -wuug was found conditionally acceptable for BLA 761152 on May 6, 2021.^a However, BLA 761152 received a Complete Response (CR) letter on 10/15/2021.^b Thus, Omeros submitted a Class 2 Resubmission on March 26, 2025.

3 Assessment of the Nonproprietary Name

We reassessed the previously conditionally acceptable suffix -wuug, using the principles described in the Nonproprietary Naming of Biological Products guidance.^c

We determined that the FDA-designated suffix -wuug, 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 May 30, 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 Non-Malignant Hematology (DNH) on June 9, 2025.

5 Conclusion

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

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for narsoplimab-wuug (BLA 761152). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 May 06. Nexus ID.: 2020-13.

^b Yanoff, L. Complete Response (BLA 761152). Silver Spring (MD): FDA, CDER, OND, OCHEN (US); 2021 Oct 15.

^c 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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/s/

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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:	June 4, 2025
Application Type and Number:	BLA 761152
Product Name, Dosage Form, and Strength:	Yartemlea (narsoplimab-xxxx) ^a injection, 370 mg/2 mL (185 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Omeros Corporation (Omeros)
PNR ID #:	2025-1044726364
DMEPA 2 Safety Evaluator:	Robbie Kattappuram, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Deputy Director	Chi-ming (Alice) Tu, PharmD

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

Table of Contents

1	INTRODUCTION	3
1.1	REGULATORY HISTORY	3
1.2	PRODUCT INFORMATION	3
2	DISCUSSION	4
2.1	MISBRANDING ASSESSMENT	4
2.2	SAFETY ASSESSMENT	4
2.2.1	United States Adopted Names (USAN) Search	4
2.2.2	Components of the Proposed Proprietary Name	4
2.2.3	Comments from Other Review Disciplines at Initial Review	4
2.2.4	FDA Prescription Simulation Studies	5
2.2.5	Phonetic and Orthographic Computer Analysis (POCA) Search Results	5
2.2.6	Names Retrieved for Review Organized by Name Pair Similarity	5
2.2.7	Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities	5
2.2.8	Communication of DMEPA's Determination	5
3	CONCLUSION	6
3.1	Comments to Omeros Corporation	6
4	REFERENCES	7
5	APPENDICES	8

1 INTRODUCTION

This review evaluates the proposed proprietary name, Yartemlea, 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. Omeros submitted an external name study, conducted by (b) (4),^b for this proposed proprietary name.

1.1 REGULATORY HISTORY

Omeros previously submitted the proposed proprietary name, Yartemlea, under IND 120524 on November 6, 2019, and we found the name conditionally acceptable on January 30, 2020.^c Omeros submitted the proposed proprietary name, Yartemlea, under BLA 761152 on November 17, 2020, and we found the name conditionally acceptable on February 12, 2021.^d The application received a Complete Response letter on October 15, 2021 due to clinical and statistical deficiencies.^e

Thus, Omeros resubmitted the proposed proprietary name, Yartemlea, for review on March 26, 2025 under BLA 761152 Class 2 resubmission.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 26, 2025^a.

Table 1. Relevant Product Information for Yartemlea	
Intended pronunciation:	yar-TEM-lee-uh
Nonproprietary name:	narsoplimab-xxxx
Indication:	treatment of patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)
Dosage Form:	injection
Strength:	370 mg/2 mL (185 mg/mL)
Route of administration:	Intravenous
Dose and frequency:	4 mg/kg once or twice weekly

^b Request for Proprietary Name Review for Yartemlea. (b) (4) 2025 MAR 26. Available from: <\\CDSESUB1\EVSPROD\bla761152\0079\m1\us\118-proprietary-names\request-for-proprietary-name-review-yartemlea.pdf>.

^c Kane, D. Proprietary Name Review for Yartemlea (IND 120524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 30. PNR ID No. 2019-35646626.

^d DeGraw, S. Proprietary Name Review for Yartemlea (BLA 761152). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 11. PNR ID No. 2020-43962569.

^e Hamilton, C on behalf of Lisa Yanoff. Complete Response for OMS721. Silver Spring (MD): FDA, CDER, OND, DNH; 2021 OCT 15. BLA 761152. Available from: <https://darrrts.fda.gov/darrrts/faces/ViewDocument?documentId=090140af8061e685>.

Table 1. Relevant Product Information for Yartemlea	
How Supplied:	370-mg (b) (4) 2-mL glass vial in a one-vial carton
Storage:	refrigerated at 2 °C to 8 °C (36 °F to 46 °F)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yartemlea 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 Yartemlea. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Yartemlea.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.^f

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Omeros did not provide a derivation or intended meaning for the proposed proprietary name, Yartemlea, in their submission. This proprietary name is comprised of a single word that contains the letter strings "rt" and "mL", which are medical abbreviations for "room temperature" and "milliliter", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviations "rt" and "mL" in the middle of the proposed proprietary name, Yartemlea, makes it unlikely for the "rt" and "mL" letter strings to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the "rt" and "mL" letter strings in this case.

Beyond these noted abbreviations, we note that PPN does not contain any additional components that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Yartemlea at the initial phase of the review.

^f USAN stem search conducted on April 28, 2025.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-two (92) practitioners participated in FDA's prescription simulation studies for Yartemlea. 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 search⁹ identified 38 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual orthographic or phonetic score of $\geq 70\%$. 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 frequency of administration from once weekly to once or twice weekly. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Yartemlea. Therefore, we identified 5 names not previously analyzed. These names are 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) 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 $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	5
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 5 names contained in Table 2 determined none of the names will pose a risk for confusion with Yartemlea as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On June 4, 2025, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

⁹ POCA search conducted on April 28, 2025 in version 5.9.

3 CONCLUSION

The proposed proprietary name, Yartemlea, is conditionally acceptable.

3.1 COMMENTS TO OMEROS CORPORATION

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

If any of the proposed product characteristics as stated in your submission, received on March 26, 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.^h

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.

^h 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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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.
 - o 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 namesⁱ. 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.

- o 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-

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

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 $\geq$ 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
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	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?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	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?	
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Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Yartemlea Study (Conducted on 4/15/25)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>yartemlea 4mg/kg intravenous infusion once</i>	Yartemlea Bring to Clinic Dispense #1 vial
<u>Outpatient Prescription:</u> Patient _____ Date <u>4/15/25</u> Address _____  Refill(s): _____ DEA No. _____ <i>yartemlea</i> <i>Bring to clinic</i> <i>#1 vial</i> Dr. <u>OSE</u> Address _____ Telephone _____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Yartemlea	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Yartemlea					
People Received Study: 161					
People Responded: 92					
Total	22	25	17	28	92
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
LARTEMLIA	0	0	1	0	1
YANTEMLEA	1	0	0	0	1
YANTERLEA	1	0	0	0	1
YARTAMLIA	0	0	1	0	1
YARTEMLA	1	2	0	0	3
YARTEMLEA	1	11	1	28	41
YARTEMLIA	0	7	12	0	19
YARTEMLYA	0	0	2	0	2
YARTENCEA	1	0	0	0	1
YARTENLEA	14	0	0	0	14
YARTENLEN	1	0	0	0	1
YARTENLER	1	0	0	0	1
YORTEMLEA	0	1	0	0	1
YORTEMLIA	0	1	0	0	1
YORTENLEA	0	1	0	0	1
YORTENLIA	0	1	0	0	1
YOUTENLIA	0	1	0	0	1
ZARTEMLEA	1	0	0	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is $\geq 70\%$)

N/A

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

N/A

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$)
with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Yartemlea Pronunciation: yar-TEM-lee-uh Established name: narsoplimab-xxxx Dosage form: injection Strength(s): 370 mg/2 mL (185 mg/mL) Dosage: 4 mg/kg once or twice weekly	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.	Dartisla	58	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F. LOW SIMILARITY NAMES (e.g., combined POCA score is $\leq 54\%$)

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
1.	(b) (4) ***	62	(b) (4)
2.	(b) (4) ***	62	

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion^j.

No.	Name	POCA Score (%)
1.	(b) (4) ***	56
2.	Starjemza***	56

^j 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/

ROBBIE S KATTAPPURAM
06/05/2025 08:24:26 PM

NICOLE F IVERSON
06/06/2025 08:26:31 AM

CHI-MING TU
06/06/2025 08:39:48 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	May 6, 2021
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761152
Product Name and Strength:	Yartemlea (narsoplimab-wuug) injection 370 mg/2 mL (185 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Omeros Corporation (Omeros)
Nexus NPNS ID:	2020-13
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761152.

1.1 Regulatory History

We note that BLA 761152 is in the scope of the Nonproprietary Naming of Biological Products Guidance. In their November 17, 2020 submission, Omeros indicated that they have not provided a list of proposed 4-letter suffixes for review and acknowledged that the Agency would designate a suffix for their nonproprietary name.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

narsoplimab-wuug

FDA generated a four-letter suffix, -wuug. This suffix was evaluated using the principles described in the applicable guidance^a.

We determined that the FDA-generated suffix -wuug, 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'S ANALYSIS

These findings were shared with OPDP. On April 27, 2021, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Non-Malignant Hematology (DNH) on May 6, 2021.

^a See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

4 CONCLUSION

We find the suffix -wuug acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to narsoplimab-wuug. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendation for Omeros Corporation

We find the nonproprietary name, narsoplimab-wuug, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, narsoplimab-wuug 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 this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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
05/07/2021 02:48:03 PM

DANIELLE M HARRIS
05/07/2021 02:48:03 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	February 11, 2021
Application Type and Number:	BLA 761152
Product Name and Strength:	Yartemlea (narsoplimab-xxxx)* injection 370 mg/2 mL (185 mg/mL)
Total Product Strength:	370 mg/2 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Omeros Corporation (Omeros)
Panorama #:	2020-43962569
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

* The nonproprietary name for this BLA has not yet been determined; therefore, the placeholder, narsoplimab-xxxx, is used throughout this review to refer to the nonproprietary name for this product.

Contents

1	INTRODUCTION	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment	2
3	CONCLUSION	3
3.1	Comments to Omeros Corporation	3
4	REFERENCES	4
	APPENDICES	5

1 INTRODUCTION

This review evaluates the proposed proprietary name, Yartemlea, 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. Omeros submitted an external name study, conducted by (b) (4), for this proposed proprietary name. This study was previously reviewed by DMEPA under the IND.

1.1 REGULATORY HISTORY

The Applicant submitted the name, Yartemlea, for review on November 6, 2019 under IND 120524. DMEPA found the name to be acceptable on January 30, 2020.^a Omeros resubmitted the name, Yartemlea, for review under the BLA on November 17, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 17, 2020.

- Intended Pronunciation: yar-TEM-lee-uh
- Active Ingredient: narsoplimab-xxxx
- Indication of Use: Treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).
- Route of Administration: Intravenous
- Dosage Form: injection
- Strength: 370 mg/2 mL (185 mg/mL)
- Dose and Frequency: 4 mg/kg administered once weekly. (b) (4)
- How Supplied: Single-use vials, one vial per carton
- Storage: Refrigerated at 2°C to 8°C in the original carton to protect from light

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yartemlea would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Nonmalignant Hematology (DNH) concurred with the findings of OPDP's assessment for Yartemlea.

^a Kane, D. Proprietary Name Review for Yartemlea (IND 120524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 30. Panorama No. 2019-35646626.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 *Components of the Proposed Proprietary Name*

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

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, January 14, 2021 e-mail, the Division of Nonmalignant Hematology (DNH) did not forward any comments or concerns relating to Yartemlea at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

Eighty-nine (89) practitioners participated in DMEPA's prescription studies for Yartemlea. 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 studies.

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search^c identified 34 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. We note that in our previous review, we evaluated the name and the identified names based on the proposed product's single strength of 185 mg/mL. The proposed strength per mL for the product is still 185 mg/mL; however, the product information submitted under the BLA states the product has a total product strength and volume of 370 mg/2 mL. Therefore, we re-evaluated the previously identified names of concern considering the new total strength of 370 mg/2 mL (185 mg/mL), as well as any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. Our re-evaluation determined 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 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. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

^b USAN stem search conducted on December 29, 2020.

^c POCA search conducted on December 29, 2020 in version 4.4.

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

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

Our analysis of the one name contained in Table 1 determined this name will not pose a risk for confusion with Yartemlea as described in Appendix E.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonmalignant Hematology (DNH) via e-mail on February 8, 2021. At that time, we also requested additional information or concerns that could inform our review. DNH did not provide additional concerns with the proposed proprietary name, Yartemlea.

3 CONCLUSION

The proposed proprietary name, Yartemlea, is acceptable.

If you have any questions or need clarifications, please contact Linda Park, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO OMEROS CORPORATION

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

If any of the proposed product characteristics as stated in your submission, received on November 17, 2020, 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. ^d

^d National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^e. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

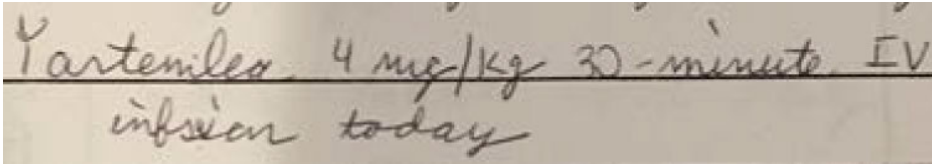
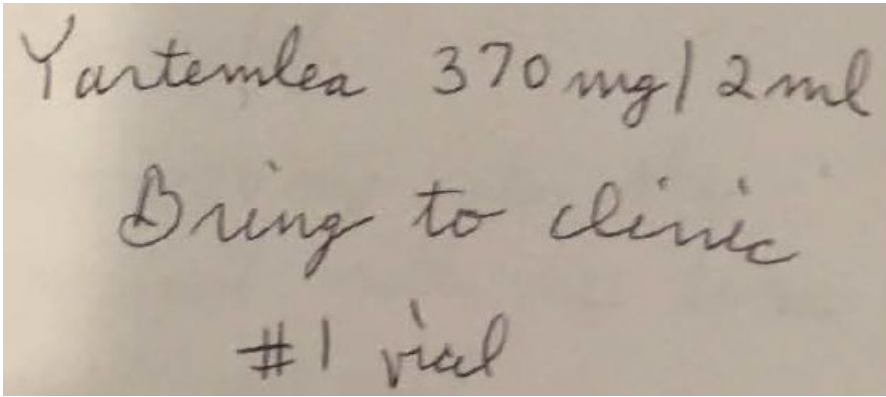
Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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. Yartemlea Study (Conducted on December 18, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Yartemlea 370 mg/2 mL Bring to clinic Dispense 1 vial
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Yartemlea	

209 People Received Study
89 People Responded

Study Name: Yartemlea

Total	34	15	14	26	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
DARTANLIA	0	0	2	0	2
DARTEMLIA	0	0	1	0	1
GARTENZA	0	0	1	0	1
JARTAMLIA	0	0	1	0	1
JARTANLIA	0	0	2	0	2
JARTEMLIA	0	0	1	0	1
JARTENDIA	0	0	1	0	1
JARTENLIA	0	0	3	0	3
JERTEMLIA	0	0	1	0	1
YARTEMILEA	0	0	0	7	7
YARTEMILEO	0	0	0	5	5
YARTEMLEA	33	15	0	1	49
YARTEMLEA 370 MG / .2ML	1	0	0	0	1
YARTEMLEO	0	0	0	4	4
YARTENILEA	0	0	0	5	5
YARTENILEO	0	0	0	3	3
YARTENILES	0	0	0	1	1
ZARTEMVIA	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$) --- N/A

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose --- N/A

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

No.	Proposed name: Yartemlea Established name: narsoplimab-xxxx Dosage form: injection Strength(s): 370 mg/2 mL (185 mg/mL) Usual Dose: 4 mg/kg once a week	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.	Yargesa***	56	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$) --- N/A

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described --- N/A

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^f --- N/A

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

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/s/

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