# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761367Orig1s000

# PROPRIETARY NAME REVIEW(S)

**SUFFIX REVIEW FOR NONPROPRIETARY NAME**
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 22, 2025 |
| **Responsible OND Division:** | Division of Pulmonology, Allergy, and Critical Care (DPACC) |
| **Application Type and Number:** | BLA 761367 |
| **Product Name and Strength:** | Andembry (garadacimab-gxii) injection<br>200 mg/1.2 mL (167 mg/mL) |
| **Product Type:** | Combination Product (Biologic-Device) |
| **Applicant/Sponsor Name:** | CSL Behring LLC (CSL) |
| **FDA Received Date:** | December 17, 2024 |
| **Nexus NPNS ID #:** | 2024-298 |
| **DMEPA 2 Biologics Suffix Specialist:** | Carlos Mena-Grillasca, BS Pharm |
| **DMEPA 1 Director:** | Mishale Mistry, PharmD, MPH |

## 1 Purpose of Review

This review is to reassess our evaluation of the four-letter suffix –gxii for BLA 761367, which was found conditionally acceptable on August 1, 2024,[a] for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761367.

## 2 Regulatory History

The proposed suffix -gxii was found conditionally acceptable for BLA 761367 on August 1, 2024.[a] However, BLA 761367 received a Complete Response (CR) letter on 10/7/2024.[b] Thus, CSL submitted a Class 2 Resubmission on December 17, 2024.

## 3 Assessment of the Nonproprietary Name

We reassessed the previously proposed suffix -gxii, using the principles described in the Nonproprietary Naming of Biological Products guidance.[c] We note that the suffix 'gxii' may connote 'garadacimab XII' in relation to the product's mechanism of action. Garadacimab is an inhibitor of activated Factor XII that binds to the catalytic domain of activated Factor XII (FXIIa and βFXIIa) and inhibits its catalytic activity. We considered whether the suffix connoting the product's mechanism of action could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -gxii, 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 1 Analysis

These findings were shared with OPDP. On March 26, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Pulmonology, Allergy, and Critical Care (DPACC) on April 22, 2025.

## 5 Conclusion

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

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for garadacimab-gxii (BLA 761367). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Aug 01. Nexus ID.: 2023-196.

[b] Donohue, K. Complete Response (BLA 761367). Silver Spring (MD): FDA, CDER, OND, Office of Immunology and Inflammation (US); 2024 Oct 07

[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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CARLOS M MENA-GRILLASCA
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MISHALE P MISTRY
04/28/2025 09:28:46 AM

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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: | February 19, 2025 |
| Application Type and Number: | BLA 761367 |
| Product Name, Dosage Form, and Strength: | Andembry (garadacimab-gxii)[a]<br>injection,<br>200 mg/1.2 mL (167 mg/mL) |
| Product Type: | Combination Product (Biologic-Device) |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | CSL Behring LLC (CSL Behring) |
| PNR ID #: | 2024-1044726259 |
| DMEPA 1 Safety Evaluator: | Lissa C. Owens, PharmD |
| DMEPA 1 Team Leader: | Damon Birkemeier, PharmD, FISMP, NREMT |
| DMEPA 1 Associate Director for Nomenclature and Labeling: | Idalia E. Rychlik, PharmD |

[a] The non-proprietary name suffix 'gxii' was found conditionally acceptable on August 6, 2024 (Nexus NPNS ID# 2023-196).

# 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Andembry, which was found conditionally acceptable under BLA 761367 on April 12, 2024.[b] CSL Behring submitted the proposed proprietary name, Andembry, under BLA 761367 for re-review on December 17, 2024.[c] We note that all product characteristics remain the same.

# 2 REGULATORY HISTORY

On October 7, 2024, the Agency issued a Complete Response (CR) letter[d] due to facility inspection, microbiology, and product quality deficiencies.

On December 17, 2024, CSL Behring submitted a class II resubmission addressing the above deficiencies.

# 3 DISCUSSION

## 3.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Andembry would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Andembry. The Division of Pulmonology, Allergy, and Critical Care (DPACC) concurred with the findings of OPDP's assessment for Andembry.

## 3.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Andembry, we 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 proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 30, 2025, search of USAN stems did not find any USAN stems in the proposed proprietary name, Andembry.

### 3.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On February 19, 2025, DMEPA 1 communicated our determination to the Division of Pulmonology, Allergy, and Critical Care (DPACC).

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[b] Owens, L. Proprietary Name Review for Andembry (BLA 761367). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 APR 12. PNR ID No. 2024-1044725568.

[c] Request for Proprietary Name (BLA 761367). King of Prussia (PA): CSL Behring LLC; 2024 DEC 17. Available from: \\CDSESUB1\EVSPROD\bla761367\0045\m1\us\102-cover\cover-reviewersguide.pdf.

[d] Ton, P. Complete Response Letter for Andembry (BLA 761367). Silver Spring (MD): FDA, CDER, OND, DPACC (US). 2024 OCT 7. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af807736c4.

## 4 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Andembry, is conditionally acceptable.

### 4.1 COMMENTS TO CSL BEHRING LLC

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

If any of the proposed product characteristics as stated in your submission, received on December 17, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

## 5 REFERENCE

*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.

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LISSA C PRINGLE-OWENS
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DAMON A BIRKEMEIER
02/20/2025 07:39:40 AM

IDALIA E RYCHLIK
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SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:** | 8/1/2024 |
| **Responsible OND Division:** | Division of Pulmonology, Allergy, and Critical Care (DPACC) |
| **Application Type and Number:** | BLA 761367 |
| **Product Name and Strength:** | Andembry (garadacimab-gxii) injection<br>200 mg/1.2 mL (167 mg/mL) |
| **Product Type:** | Combination Product (Biologic-Device) |
| **Applicant/Sponsor Name:** | CSL Behring LLC (CSL) |
| **FDA Received Date:** | October 13, 2023 |
| **Nexus NPNS ID #:** | 2023-196 |
| **DMEPA 2 Biologics Suffix Specialist:** | Carlos M Mena-Grillasca, BS Pharm |
| **DMEPA 1 Director:** | Mishale Mistry, PharmD, MPH |

## 1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by CSL for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761367.

## 2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 13, 2023, CSL submitted a list of ten suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. CSL also provided findings from an external study conducted by (b) (4)[a], evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by CSL:

**Table 1. Suffixes submitted by CSL*****

| | |
|---|---|
| 1. | gxii |
| 2. | (b) (4) |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |
| 9. | |
| 10. | |

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

[a] Biological Proper Name Suffix Request BLA 761367. King of Prussia (PA): CSL Behring LLC; 2023 Oct 13. Available from: \\Cdsesub1\evsprod\BLA761367\0001\m1\us\118-proprietary

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

### 2.1 garadacimab-gxii

CSL's first proposed suffix, -gxii, is comprised of three distinct letters (g, x, i).

We determined that the proposed suffix -gxii, 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 1 ANALYSIS

These findings were shared with OPDP. On July 17, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Pulmonology, Allergy, and Critical Care (DPACC) on August 1, 2024.

## 4 CONCLUSION

We find CSL's proposed suffix -gxii acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to garadacimab-gxii. DMEPA 1 will communicate our findings to the Applicant via letter.

### 4.1 Recommendations for CSL Behring LLC

We find the nonproprietary name, garadacimab-gxii, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, garadacimab-gxii 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.

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MISHALE P MISTRY
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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 12, 2024 |
| Application Type and Number: | BLA 761367 |
| Product Name, Dosage Form, and Strength: | Andembry (garadacimab-xxxx)[a] injection, 200 mg/1.2 mL (170 mg/mL) |
| Product Type: | Combination Product (Biologic-Device) |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | CSL Behring (CSL Behring) |
| PNR ID #: | 2024-1044725568 |
| DMEPA 1 Safety Evaluator: | Lissa C. Owens, PharmD |
| DMEPA 1 Team Leader: | Damon Birkemeier, PharmD, FISMP, NREMT |
| DMEPA 1 Director: | Mishale Mistry, PharmD, MPH |

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder garadacimab-xxxx-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, Andembry, 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. CSL Behring submitted an external name study, conducted by [redacted][b], for this proposed proprietary name.

### 1.1 REGULATORY HISTORY

CSL Behring previously submitted the proposed proprietary name, [redacted]*** under BLA 761367 on June 29, 2023. However, on August 31, 2023, we found the name, [redacted]*** unacceptable due to misbranding concerns.[c]

Subsequently, BLA 761367 received a Refusal to File (RTF) Notification[d] on August 28, 2023, and our comments regarding the proprietary name were not communicated to the Applicant. Therefore, CSL Behring re-submitted the BLA and proposed proprietary name, [redacted]*** for review on October 13, 2023.

On November 29, 2023, we found the name, [redacted]*** unacceptable due to misbranding concerns.[e]

Thus, CSL Behring submitted the proposed proprietary name, Andembry, for review on January 16, 2024, under BLA 761367.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 16, 2024.[f]

| **Table 1. Relevant Product Information for Andembry** | |
|---|---|
| **Intended pronunciation:** | an-DEM-bree |
| **Nonproprietary name:** | garadacimab-xxxx |
| **Indication:** | prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older |
| **Dosage Form:** | injection |

[b] Request for Proprietary Name. [redacted]; 2023 MAY. Available from: \\CDSESUB1\EVSPROD\bla761367\0015\m1\us\102-cover\cover.pdf .

[c] Vee, S. Proprietary Name Review for [redacted]*** (BLA 761367). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 AUG 31. PNR ID No. 2023-1044725210.

[d] https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af806ee737

[e] Owens, L. Proprietary Name Review for [redacted]*** (BLA 761367). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 NOV 29. PNR ID No. 2023-1044725420.

[f] Request for Proprietary Name Review BLA 761367. King Prussia (PA): CSL Behring; 2024 JAN 16. Available from: \\CDSESUB1\EVSPROD\bla761367\0015\m1\us\102-cover\cover.pdf

| Table 1. Relevant Product Information for Andembry | |
|---|---|
| **Strength:** | 200 mg/1.2 mL (170 mg/mL) |
| **Route of administration:** | subcutaneous |
| **Dose and frequency:** | initial loading dose of 400 mg, administered subcutaneously as two 200 mg injections on the first day of treatment, followed by a subcutaneous monthly dose of 200 mg |
| **How Supplied:** | ready-to-use, clear to slightly opalescent to clear, brownish-yellow to yellow solution in the following presentations, supplied in single-dose prefilled pen or prefilled syringe with needle safety device.<br><br>Each single-dose prefilled pen or prefilled syringe with needle safety device is supplied in a carton |
| **Storage:** | Store the prefilled pen and prefilled syringe with needle safety device refrigerated at 36°F to 46°F (2°C - 8°C).<br>(b) (4) |

## 2 DISCUSSION

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Andembry would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Andembry. The Division of Pulmonology, Allergy, and Critical Care (DPACC) concurred with the findings of OPDP's assessment for Andembry.

### 2.2 SAFETY ASSESSMENT

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

#### 2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[g] USAN stem search conducted on March 4, 2024.

### 2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

### 2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On February 7, 2024, the Division of Pulmonology, Allergy, and Critical Care (DPACC) did not forward any comments or concerns relating to Andembry at the initial phase of the review.

### 2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-three (n=83) practitioners participated in DMEPA's prescription simulation studies for Andembry. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

### 2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[h] identified 51 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 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:<br>combined match percentage score ≥70% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 50 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 4 |

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

Our analysis of the 55 names contained in Table 2 determined none of the names will pose a risk for confusion with Andembry as described in Appendices C through H.

[h] POCA search conducted on March 4, 2024 in version 5.5.

### 2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 11, 2024, DMEPA 1 communicated our determination to the Division of Pulmonology, Allergy, and Critical Care (DPACC).

## 3 CONCLUSION

The proposed proprietary name, Andembry, is conditionally acceptable.

If you have any questions or need clarifications, please contact Cristina Attinello, OSE project manager, at 301-796-3986.

### 3.1 COMMENTS TO CSL BEHRING

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

A request for proprietary name review for Andembry should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on January 16, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

## 4 REFERENCES

*1. United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

*2. Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

*Drugs@FDA*

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs@FDA Glossary of Terms, available at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

*RxNorm*

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

*Purple Book*

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

*Division of Medication Errors Prevention and Analysis pending proprietary name requests*

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

# 5 APPENDICES

## APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[i]

| *Table 3. Prescreening Checklist for Proposed Proprietary Name<br>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. |

[i] 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<br>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[j]. 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. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

[j] Shah, M, Merchant, L, 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?<br>*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?<br>**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? | | |

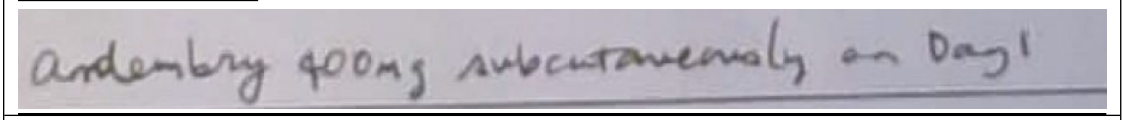
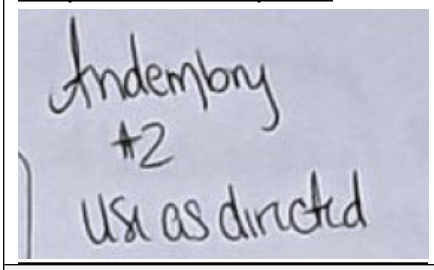
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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.<br>For single strength products, also consider circumstances where the strength may not be expressed.<br>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.<br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br>• 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.<br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br>• 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)<br>• Do the names begin with different first letters?<br>• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>• *FDA considers the length of names different if the names differ by two or more letters.<br>• 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)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• 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?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• 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. Andembry Study (Conducted on 1/26/2024)

| Handwritten Medication Order Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br><br>Outpatient Prescription:<br>  <br> | Andembry<br>Use as directed<br>#2 |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font) | |
| **Andembry** | |

# Aggregate Report

As of Date: 03/06/2024 10:28

**Study Name:** Andembry - 2024-01-26

**People Received Study:** 165

**People Responded:** 83

| Total | 22 | 18 | 23 | 20 | 83 |
|---|---|---|---|---|---|
| **INTERPRETATION** | **INPATIENT** | **OUTPATIENT** | **VOICE** | **CPOE** | **TOTAL** |
| ADEMBRY | 0 | 1 | 0 | 0 | 1 |
| AMMENS | 0 | 0 | 0 | 1 | 1 |
| ANDEMBNY | 0 | 2 | 0 | 0 | 2 |
| ANDEMBRI | 0 | 0 | 7 | 0 | 7 |
| ANDEMBRY | 20 | 13 | 7 | 19 | 59 |
| ANDEMLBRY | 1 | 0 | 0 | 0 | 1 |
| ARDEMBRY | 1 | 0 | 0 | 0 | 1 |
| ENDEMBREE | 0 | 0 | 1 | 0 | 1 |
| ENDEMBRI | 0 | 0 | 3 | 0 | 3 |
| ENDEMBRY | 0 | 0 | 1 | 0 | 1 |
| ENDEMVY | 0 | 0 | 1 | 0 | 1 |
| IANDEMBRY | 0 | 0 | 1 | 0 | 1 |
| IANDEMPRI | 0 | 0 | 1 | 0 | 1 |
| INDEMBRE | 0 | 0 | 1 | 0 | 1 |
| INDEMBRY | 0 | 1 | 0 | 0 | 1 |
| INDEMLORY | 0 | 1 | 0 | 0 | 1 |

** U.S. FDA - RX Study*

** RX Study Version 4.7 (2023-12-26)*

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

| No. | Proposed name: Andembry<br>Established name: garadacimab-xxxx<br>Dosage form: injection<br>Strength(s): 200 mg/1.2 mL (170 mg/mL)<br>Dosage: 400 mg initially followed by 200 mg once monthly | POCA Score (%) | Orthographic and/or phonetic differences in the names sufficient to prevent confusion<br><br>Other prevention of failure mode expected to minimize the risk of confusion between these two names. |
|---|---|---|---|
| 1. | Andembry | 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. | Ambien CR | 63 |
| 2. | Dandrene | 58 |

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: Andembry<br>Established name: garadacimab-xxxx<br>Dosage form: injection<br>Strength(s): 200 mg/1.2 mL (170 mg/mL)<br>Dosage: 400 mg initially followed by 200 mg once monthly | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 1. | Tandem OB | 67 | This name pair has sufficient orthographic and phonetic differences. |
| 2. | Myfembree | 65 | This name pair has sufficient orthographic and phonetic differences. |
| 3. | Adbry | 62 | Orthographically, Andembry is longer when scripted than Adbry (8 letters *versus* 5 letters). The additional letters '-em-'in the infix of Andembry provide some orthographic differences.<br><br>Phonetically, Andembry contains an additional syllable (3 *versus* 2). The first (An *versus* Ad) and second (dem *versus* bry) offer some additional phonetic differences.<br><br>In addition to the orthographic and phonetic differences, the following product characteristics may help to minimize the risk of error:<br>• Dose and Frequency: Andembry is administered as 400 mg initially followed by 200 mg once monthly. Adbry is administered as 600 mg (four 150 mg injections), or 300 mg (two 150 mg injections) initially followed by 300 mg (two 150 mg injections) or 150 mg (one 150 injection) every other week, a dosage of 300 mg every 4 weeks may be considered for adult patients below 100 kg who achieve clear or almost |

| No. | Proposed name: Andembry<br>Established name: garadacimab-xxxx<br>Dosage form: injection<br>Strength(s): 200 mg/1.2 mL (170 mg/mL)<br>Dosage: 400 mg initially followed by 200 mg once monthly | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| | | | clear skin after 16 weeks of treatment. It is likely that dosing instructions would have to be included on a prescription/ medication order for either product.<br><br>When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case. |
| 4. | Tandem F | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 5. | Depandro 100 | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Tevimbra*** | 59 | This name pair has sufficient orthographic and phonetic differences. |
| 7. | (b) (4) *** | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 8. | Zembrace | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | Tandem | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 10. | Tandem Plus | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 11. | Mandelay | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 12. | Actemra | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 13. | Adzynma | 56 | This name pair has sufficient orthographic and phonetic differences. |

| No. | Proposed name: Andembry<br>Established name: garadacimab-xxxx<br>Dosage form: injection<br>Strength(s): 200 mg/1.2 mL (170 mg/mL)<br>Dosage: 400 mg initially followed by 200 mg once monthly | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 14. | Adzenys ER | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 15. | Dandrex | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 16. | Xdemvy | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 17. | Androderm | 56 | Orthographically, Andembry contains a downstroke letter 'y' in the suffix not present in Androderm which makes the shape of the names appear different.<br><br>Phonetically, the ending of the second syllable (dem *versus* dro) and the third syllable (bry *versus* derm) sound different.<br><br>In addition to the orthographic and phonetic differences, the following product characteristics may help to minimize the risk of error:<br>• Dose and Frequency: Andembry is 400 mg initially followed by 200 mg once monthly *versus* Androderm which is 2 mg, 4 mg, or 6 mg applied nightly for 24 hours.<br>• Dosage Form: There is no overlap in dosage form, if included on a prescription/medication order (injection *versus* transdermal system).<br>• Route of administration: There is no overlap in route of administration, if included on a prescription/medication order (subcutaneous *versus* topical). |

| No. | Proposed name: Andembry<br>Established name: garadacimab-xxxx<br>Dosage form: injection<br>Strength(s): 200 mg/1.2 mL (170 mg/mL)<br>Dosage: 400 mg initially followed by 200 mg once monthly | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| | | | When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case. |
| 18. | Amber | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 19. | Maldemar | 55 | This name pair has sufficient orthographic and phonetic differences. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Enbrel | 46 |
| 2. | Androgel | 45 |
| 3. | Admelog | 36 |
| 4. | Atenolol | 28 |

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. | Andec-TR | 66 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 2. | Ambodryl | 66 | Brand discontinued with no generic equivalents available. NDA 007984 withdrawn FR effective 11/05/1992. |
| 3. | (b) (4) *** | 64 | Proposed proprietary name for IND (b) (4) found to be acceptable (OSE (b) (4)), however, the application has been inactive since (b) (4). |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 4. | Adizem-SR | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 5. | Antimony | 60 | Product is not a drug. It is a chemical element. |
| 6. | (b) (4) *** | 60 | Proposed proprietary name for IND 105081 found unacceptable by DMEPA (OSE 2020-43909644 dated December 9, 2020). Associated BLA 761269 approved under the proprietary name Leqembi. |
| 7. | Metandren | 60 | Brand discontinued with no generic equivalents available. NDA 003240 withdrawn FR effective 11/05/1992. |
| 8. | Adipine MR 10 | 59 | International product marketed in United Kingdom, Thailand, and Poland. |
| 9. | Adipine MR 20 | 59 | International product marketed in United Kingdom, Thailand, and Poland. |
| 10. | Albadry | 58 | Veterinary product. |
| 11. | Avandaryl | 58 | Brand discontinued with no generic equivalents available. NDA 021700 withdrawn FR effective November 19, 2018. |
| 12. | Ambenyl | 58 | Brand discontinued with no generic equivalents available. NDA 009319 withdrawn FR effective 12/7/2007. |
| 13. | Andryl 200 | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 14. | (b) (4) *** | 57 | Proposed proprietary name for IND (b) (4) found to be unacceptable (OSE # (b) (4)). Entire application withdrawn by the Applicant on (b) (4). |
| 15. | Antepar | 56 | Brand discontinued with no generic equivalents available. NDA 009102 withdrawn FR effective 04/26/1996. |
| 16. | Androxy | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 17. | Tanderil | 55 | Name identified in RxNorm. Unable to find product characteristics in commonly used databases. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Benadryl | 60 |
| 2. | E-Z-Cat Dry | 60 |
| 3. | (b) (4) *** | 60 |
| 4. | Cedramber | 58 |
| 5. | Endometrin | 58 |
| 6. | Penbraya | 58 |
| 7. | Lantidra | 57 |
| 8. | Ixempra | 56 |
| 9. | Phendry | 56 |
| 10. | Savlon Dry | 56 |
| 11. | Stendra | 56 |
| 12. | Venbid TR | 56 |

[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.

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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.**

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/s/

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LISSA C PRINGLE-OWENS
04/11/2024 08:56:06 PM

DAMON A BIRKEMEIER
04/12/2024 07:35:21 AM

MISHALE P MISTRY
04/12/2024 09:01:48 AM

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:** | November 29, 2023 |
| **Application Type and Number:** | BLA 761367 |
| **Product Name and Strength:** | (b) (4) (garadacimab-xxxx)[a] injection, 200 mg/1.2 mL |
| **Product Type:** | Combination Product (Biologic-Device) |
| **Rx or OTC:** | Choose an item |
| **Applicant/Sponsor Name:** | CSL Behring (CSL Behring) |
| **PNR ID #:** | 2023-1044725420 |
| **DMEPA 1 Safety Evaluator:** | Lissa C. Owens, PharmD |
| **DMEPA 1 Team Leader:** | Idalia E. Rychlik, PharmD |
| **DMEPA 1 Director:** | Mishale Mistry, PharmD, MPH |

7 Page(s) have been Withheld in Full as b4 (CCI/TS) immediately following this page

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

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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.**

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/s/

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LISSA C PRINGLE-OWENS
11/29/2023 12:04:28 PM

MISHALE P MISTRY on behalf of IDALIA E RYCHLIK
11/29/2023 05:21:12 PM
Signed on behalf of Idalia Rychlik

MISHALE P MISTRY
11/29/2023 05:22:08 PM