CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761432Orig1s000

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:	3/19/2025
Responsible OND Division:	Division of Antivirals (DAV)
Application Type and Number:	BLA 761432
Product Name and Strength:	Enflonsia (clesrovimab-cfor) injection, 105 mg/0.7 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC (Merck)
FDA Received Date:	November 18, 2024
Nexus NPNS ID #:	2024-271
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Reference ID: 5553975

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Merck for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761432.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 18, 2024, Merck submitted a list of six suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by Merck:

Table 1. Suffixes submitted by Merck***

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

We reviewed Merck's proposed suffixes in the order of preference listed by Merck, using the principles described in the applicable guidance.[b]

2.1 clesrovimab-1st cfor

Merck's first proposed suffix, -cfor, is comprised of 4 distinct letters.

The proposed suffix -cfor, contains the United States Adopted Name (USAN) stem '-fo-' in the infix position of the suffix. The USAN stem '-fo-' is used by the USAN Council to indicate phosphor-derivative containing products. We evaluated the presence of this two letter USAN stem in the

[a] Non-Proprietary Name Suffix Review BLA 761432. Rahway (NJ): Merck Sharp & Dohme LLC; 2024 Nov 18. Available from: \\CDSESUB1\EVSPROD\bla761432\0009\m1\us\multi-module-info-amendment-20241118.pdf

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

context of a 4-letter suffix and determined that in this case, the presence of this USAN stem in this suffix is unlikely to increase the risk of confusion or medication errors. Therefore, we do not object to the proposed proprietary name based on the presence of a USAN stem in this instance.

In addition, we note that the letters 'cf' in the suffix represent the medical abbreviation for 'cold formula'. We considered whether the inclusion of the letters 'cf' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -cfor, 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 March 19, 2025, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Antivirals (DAV) on March 19, 2025.

4 CONCLUSION

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

4.1 Recommendations for Merck Sharp & Dohme LLC

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

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
03/19/2025 07:26:25 PM

MISHALE P MISTRY
03/20/2025 01:55:06 PM

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:	February 26, 2025
Application Type and Number:	BLA 761432
Product Name, Dosage Form, and Strength:	Enflonsia (clesrovimab) injection, 105 mg/0.7 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC (Merck)
PNR ID #:	2024-1044726205
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia Rychlik, PharmD

Reference ID: 5539864

Table of Contents

Reference ID: 5539864

1 INTRODUCTION

This review evaluates the proposed proprietary name, Enflonsia, 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. Merck did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Merck previously submitted the proposed proprietary name, [redacted] (b) (4) *** under BLA 761432 on October 14, 2024. DMEPA found the name, [redacted] (b) (4) *** conditionally acceptable on December 11, 2024[a], however, Merck withdrew the proposed proprietary name, [redacted] (b) (4) *** on December 20, 2024.

Thus, Merck submitted the proposed proprietary name, Enflonsia, for review on December 20, 2024 under BLA 761432.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 20, 2024[b]

Table 1. Relevant Product Information for Enflonsia	
Intended pronunciation:	En-flahn-see-ah
Nonproprietary name:	clesrovimab
Indication:	Indicated for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.
Dosage Form:	injection
Strength:	105 mg/0.7mL
Route of administration:	intramuscular
Dose and frequency:	105 mg as a single intramuscular injection
How Supplied:	Sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution supplied as follows: Carton containing one or ten single-dose prefilled type I glass syringe(s) with Luer Lock and plunger stopper. The prefilled syringe is not made with natural rubber latex.

[a] Fanari, M. Proprietary Name Review for [redacted] (b) (4) *** (BLA 761432). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Dec 11. PNR ID No. 2024-1044726038

[b] Request for proprietary Name Review (BLA 761432; Enflonsia). Rahway (NJ): Merck Sharp & Dohme LLC; 2024 Dec 20. Available from: \\CDSESUB1\evsprod\BLA761432\0019\m1\us.

Table 1. Relevant Product Information for Enflonsia	
Storage:	• Store prefilled syringes under refrigeration at 36°F to 46°F (2°C to 8°C). • Keep the prefilled syringe in the original carton to protect from light until time of use. • May be kept at room temperature between 68°F to 77°F (20°C to 25°C) for a maximum of 48 hours. After removal from the refrigerator, must be used within 48 hours or discarded. • Do not freeze. Do not shake.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Enflonsia 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, however, the Division of Antivirals (DAV) did not concur with OPDP's assessment. The Division of Antivirals (DAV) expressed concerns "that Enflonsia sounds similar to influenza and to the drug Flonase and may lead to medication errors."

In response to DAV's comments OPDP re-evaluated the proposed proprietary name "Enflonsia" and provided the following comments:

> *OPDP maintains our non-objection to "Enflonsia" from a promotional perspective. The proposed indication is for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. The OPDP PNR team discussed whether the proposed proprietary name could potentially evoke the word "influenza," however, the consensus of the team was that the connection between the proposed proprietary name and influenza was not sufficiently definitive to support an objection. According to the sponsor's request for proprietary name review, the intended pronunciation of the proposed proprietary name is "en-flahn-see-ah." Given the phonetic differences between "en" and "flahn," as evoked by Enflonsia, compared to "in" and "flu," as evoked by influenza, OPDP has determined that the proposed proprietary name is not false or misleading from a promotional perspective. We appreciate the feedback from DAV and the opportunity to re-evaluate this proposed proprietary name, but we respectfully maintain our non-objection. OPDP will closely monitor any future promotional materials for any false or misleading claims related to the concerns raised by DAV. OPDP defers to DMEPA's safety evaluation of the proposed proprietary name to determine whether similarity to the marketed product Flonase could lead to medication error*.

In response to OPDP's reassessment DAV concurred with the above conclusion and did not request further discussion.

See Appendix E for DMEPA's evaluation of the name pair 'Enflonsia' and 'Flonase'.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Merck did not provide a derivation or intended meaning for the proposed proprietary name, Enflonsia, in their submission. This proprietary name is comprised of a single word that contains the letter strings "ns" and "ia", which are medical abbreviations for "normal saline or nasal spray", and "intra-arterial" respectively. We determined that the location of the abbreviation "ns" in the middle of the proposed proprietary name, Enflonsia, makes it unlikely for the "ns" letter string 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 "ns" letter string in this case. Furthermore, we evaluated if the proposed name Enflonsia could be interpreted as "Enflons IA", with "IA" as a modifier. A POCA search of the name "Enflons" did not identify any names that would pose a risk for confusion.[d]

Beyond these noted abbreviations, we note that Enflonsia does not contain any additional components (i.e., 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

The Division of Antivirals (DAV) expressed concerns with the proposed proprietary name Enflonsia (see section 2.1).

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (n=84) practitioners participated in DMEPA's prescription simulation studies for Enflonsia. 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.

[c] USAN stem search conducted on January 13, 2025.

[d] POCA search for 'Enflons' conducted on February 19, 2025.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[e] identified 79 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 the name identified by the Division of Antiviral's clinical review team. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	66
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 79 names contained in Table 2 determined none of the names will pose a risk for confusion with Enflonsia as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 26, 2025, DMEPA 1 communicated our determination to the Division of Antivirals (DAV).

3 CONCLUSION

The proposed proprietary name, Enflonsia, is conditionally acceptable.

3.1 COMMENTS TO MERCK SHARP & DOHME LLC

We have completed our review of the proposed proprietary name, Enflonsia, 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 20, 2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

[e] POCA search conducted on January 13, 2025 in version 5.9.

APPEARS THIS WAY ON ORIGINAL

Reference ID: 5539864

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.[f]

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)).

[f] 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	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, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Tables 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category that cross-references the respective table that addresses criteria that DMEPA

uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. 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.

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

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-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).
Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**	
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.

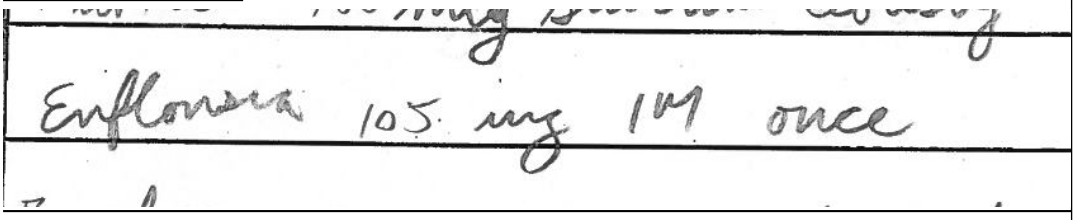
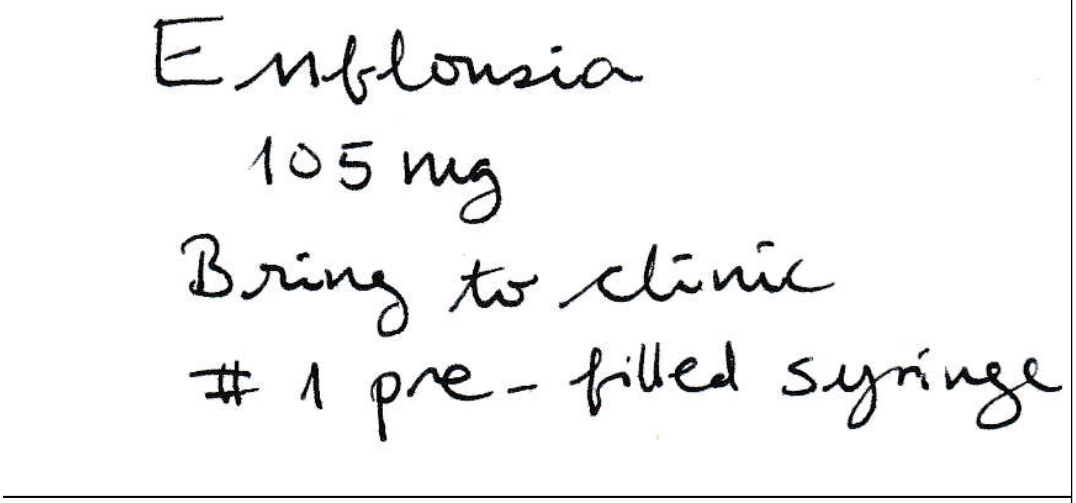
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the names 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 as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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.

APPEARS THIS WAY ON ORIGINAL

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Enflonsia Study (Conducted on 1/17/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Enflonsia 105 mg Bring to clinic #1 pre-filled syringe
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Enflonsia	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Enflonsia - 2025-01-17 People Received Study: 167 People Responded: 84					
Total	25	22	16	21	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
EMBLONSIA	0	1	0	0	1
EMFLONSIA	0	2	0	0	2
EMFLOUSIA	0	1	0	0	1
ENBLONSIA	0	2	0	0	2
ENBLOUSIA	0	1	0	0	1
ENFFOMISA	0	1	0	0	1
ENFLANCIA	0	0	2	0	2
ENFLANTYSYE	0	0	1	0	1
ENFLANTZIA	0	0	1	0	1
ENFLAUNCIA	0	0	1	0	1
ENFLONCEA	0	0	1	0	1
ENFLONCIA	0	0	4	0	4
ENFLONOVA	1	0	0	0	1
ENFLONSEA	4	0	0	0	4
ENFLONSIA	13	6	2	21	42
ENFLONSRA	3	0	0	0	3
ENFLOSIA	1	0	0	0	1

ENFLOUSIA	1	7	0	0	8
ENSLACIA	0	0	1	0	1
ENSOLNSIA	0	0	1	0	1
ENVLANCIA	0	0	1	0	1
EUFLONSEA	1	0	0	0	1
EVIFLOUSEA	1	0	0	0	1
INFLONCIA	0	0	1	0	1
RNFLONSIA	0	1	0	0	1

Reference ID: 5539864

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

No.	Proposed name: Enflonsia Pronunciation: En-flahn-see-ah Established name: clesrovimab Dosage form: injection Strength(s): 105 mg/0.7 mL Dosage: 105 mg as a single intramuscular injection	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Enflonsia	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.	Aptensio	58
2.	Adhansia	56

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

No.	Proposed name: Enflonsia Pronunciation: En-flahn-see-ah Established name: clesrovimab Dosage form: injection Strength(s): 105 mg/0.7 mL Dosage: 105 mg as a single intramuscular injection	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.	Inflectra	64	This name pair has sufficient orthographic and phonetic differences.
2.	Intelence	62	This name pair has sufficient orthographic and phonetic differences.
3.	Eprontia	62	This name pair has sufficient orthographic and phonetic differences.
4.	Renflexis	62	This name pair has sufficient orthographic and phonetic differences.
5.	Enlon-Plus	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Enflonsia Pronunciation: En-flahn-see-ah Established name: clesrovimab Dosage form: injection Strength(s): 105 mg/0.7 mL Dosage: 105 mg as a single intramuscular injection	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
6.	Infliximab	60	This name pair has sufficient orthographic and phonetic differences.
7.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
8.	Flonase	58	The prefix “En vs. Fl” affords some orthographic difference between the name pair. Phonetically, the name Enflonsia contains four syllables vs. Flonase contains two syllables. Additionally, the first syllables (“En” *versus* “Flow”) and last syllables (“ah” *versus* “nase”) sound different when spoken. Flonase is available in 4 formulations (allergy relief, sensimist allergy relief, headache and allergy relief, nighttime allergy relief) which would need to be specified on a prescription. Additionally, the products differ in dose (105 mg vs 50 mcg or 27.5 mcg [1 -2 spray], 325 mg/2 mg/5 mg [2 caplets] or 2.5 mg [1 tablet]), strength (105 mg/0.7 mL vs. 50 mcg or 27.5 mcg per spray, 325 mg/2 mg/5 mg or 2.5 mg) and dosage form (solution vs. nasal spray or caplet/tablet), route of administration (injection vs. intranasal or oral) and frequency of administration (once vs. 4-6 hours or once daily) which when included on a prescription may help to further differentiate the products.

No.	Proposed name: Enflonsia Pronunciation: En-flahn-see-ah Established name: clesrovimab Dosage form: injection Strength(s): 105 mg/0.7 mL Dosage: 105 mg as a single intramuscular injection	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
			Thus, in this specific case, the risk of name confusion between this name pair is minimized.
9.	(b) (4) **	58	This name pair has sufficient orthographic and phonetic differences.
10.	Omlonti	58	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4) **	58	This name pair has sufficient orthographic and phonetic differences.
12.	Zynlonta	58	This name pair has sufficient orthographic and phonetic differences.
13.	Elepsia	56	This name pair has sufficient orthographic and phonetic differences.
14.	Emflaza	56	This name pair has sufficient orthographic and phonetic differences.
15.	Enlon	56	This name pair has sufficient orthographic and phonetic differences.
16.	Entadfi	56	This name pair has sufficient orthographic and phonetic differences.
17.	Besponsa	56	This name pair has sufficient orthographic and phonetic differences.
18.	Inflamase Mild	56	This name pair has sufficient orthographic and phonetic differences.
19.	Celontin	55	This name pair has sufficient orthographic and phonetic differences.
20.	Deconsal L.A.	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.	(b) (4) **	54
2.	Flixonase	52
3.	Eflone	52
4.	Phenylfenesin La	52
5.	Peoniflorin	51
6.	Flosequinan	50
7.	Ilosone Sulfa	50
8.	Lotensin	50
9.	Flonase Sensimist***	48
10.	Lofena	48
11.	Fennel Oil	46
12.	Efasin	46

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.	Solensia	68	Veterinary product.
2.	(b) (4) ***	66	Proposed proprietary name for NDA 208751 found to be unacceptable by DMEPA (OSE# 2016-8522346-1). NDA 208751 (now BLA 208751) approved under the proprietary name Fiasp.
3.	Enroflox	61	Veterinary product.
4.	Enfolast-N	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Tensilon	60	Brand discontinued with no generic equivalents available. NDA 007959 withdrawn FR effective 05/23/2024.
6.	Efloxate	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Enflurane	60	Brand discontinued with no generic equivalents available. ANDA 070803 and ANDA 074396 withdrawn FR effective 11/02/2017 and 07/21/2017.

No.	Name	POCA Score (%)	Failure preventions
8.	Consensi	59	Brand discontinued with no generic equivalents available. NDA 210045 withdrawn FR effective 01/09/2023.
9.	(b) (4) ***	58	Proposed proprietary name for NDA 210566 found unacceptable by DMEPA (2017- 19081749; 01/22/2018). Application is approved under proprietary name Lexette.
10.	(b) (4) ***	58	Proposed proprietary name for IND 122955 found unacceptable by DMEPA (OSE# 2017-13929692 dated 07/21/2017). NDA 218490 approved 3/22/2024 under the proprietary name Opsynvi.
11.	Ephensin-La	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Nuelin S.A.	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases, however, Nuelin is an international product marketed in numerous international countries.
13.	Lofensaid	56	International product formally marketed in the UK.
14.	Isoflavones	56	Product is not a drug, it is a type of plant compound found in legumes.
15.	Endoxana	56	International product marketed in Ireland, Thailand and UK.
16.	Enrofloxacin	56	Veterinary product.
17.	Enterocina	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	(b) (4) ***	56	Proposed proprietary name for IND 073916 found unacceptable by DMEPA (OSE# 2018-21548167-1). NDA 212950 approved under the proprietary name Rukobia.
19.	Floxin I.V.	56	Brand discontinued with no generic equivalents available. NDA 020087 withdrawn FR effective 06/18/2009.
20.	Onsolis	55	Brand discontinued with no generic equivalents available. NDA 022266 withdrawn FR effective 01/09/2023.

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

No.	Name	POCA Score (%)
1.	Nafrinse	62
2.	Diflunisal	60
3.	Gen-Lanta	60
4.	Flunisin	59
5.	Sani-Clens	59
6.	Unisomnia	59
7.	Fluorinse	58
8.	Ventolin Hfa	58
9.	Slo-Niacin	57
10.	Anaflex	56
11.	Anthelios 20	56
12.	Anthelios 40	56
13.	Anti Cleanse	56
14.	Deslanoside	56
15.	Fensolvi	56
16.	Gen-Lanta Ii	56
17.	Inclisiran	56
18.	(b) (4) ***	56
19.	Lidosense	56
20.	(b) (4) ***	56
21.	Senexon S	56
22.	Handclens	55
23.	(b) (4) ***	55
24.	Intron A	55

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

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

/s/

MELINA N FANARI
02/26/2025 04:29:23 PM

YEVGENIYA M KOGAN
02/26/2025 05:07:08 PM

IDALIA E RYCHLIK
02/27/2025 05:25:55 PM

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:	December 11, 2024
Application Type and Number:	BLA 761432
Product Name, Dosage Form, and Strength:	(b) (4) (clesrovimab-xxxx)[a] injection, 105 mg/0.7mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC (Merck)
PNR ID #:	2024-1044726038
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia Rychlik, PharmD

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

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

Reference ID: 5493963

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/

MELINA N FANARI
12/11/2024 01:33:01 PM

YEVGENIYA M KOGAN
12/11/2024 01:45:33 PM

IDALIA E RYCHLIK
12/11/2024 02:13:58 PM