CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761427Orig1s000

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:	October 2, 2025
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761427
Product Name and Strength:	Lerochol (lerodalcibep-liga) injection, 300 mg/1.2 mL (250 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	LIB Therapeutics, Inc. (LIB Therapeutics)
FDA Received Date:	December 12, 2024
Nexus NPNS ID #:	2024-283
DMEPA 1 Biologics Suffix Specialist:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 Purpose of Review

This review summarizes our evaluation of the four-letter suffixes proposed by LIB Therapeutics for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761427.

2 Assessment of the Nonproprietary Name

On December 12, 2024, LIB Therapeutics submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product and 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 the list of suffixes submitted by LIB Therapeutics:

Table 1

	Suffixes submitted by LIB Therapeutics
1.	liga
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

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

2.1 lerodalcibep–liga

LIB Therapeutics's first proposed suffix, -liga, is comprised of 4 distinct letters.

We determined that the proposed suffix -liga, 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 be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 Communication of DMEPA 1 Analysis

[a] Data Summary for Proposed Suffixes BLA 761427. (b) (4) 2024 NOV 21. Available from: \\CDSESUB1\EVSPROD\bla761427\0001\m1\us\118-proprietary-names\proposed-suffixes.pdf

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

These findings were shared with OPDP. On October 1, 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 Diabetes, Lipid Disorders, and Obesity (DDLO) on October 2, 2025.

4 Conclusion

We find LIB Therapeutics's proposed suffix –liga acceptable. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for LIB Therapeutics, Inc.

We find the nonproprietary name, lerodalcibep-liga, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, lerodalcibep-liga will be the proper name designated in the license. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated. 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 on behalf of MADHURI R PATEL
10/02/2025 06:11:03 PM
Uploaded on behalf of Madhuri Patel

IDALIA E RYCHLIK
10/03/2025 08:21:22 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)

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Date of This Review:	February 19, 2025
Application Type and Number:	BLA 761427 and IND 134579
Product Name, Dosage Form, and Strength:	Lerochol (lerodalcibep-xxxx)[a] injection, 300 mg/1.2 mL (250 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	LIB Therapeutics (LIB)
PNR ID #:	2024-1044726167 (BLA 761427) 2024-1044725982 (IND 134579)
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "lerodalcibep-xxxx" throughout this review in place of the nonproprietary name for this product.

Table of Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

LIB submitted the proposed proprietary name, Lerochol, under IND 134579 on September 13, 2024. Subsequently, LIB submitted the proposed proprietary name, Lerochol, under BLA 761427 on December 16, 2024. This review evaluates the proposed proprietary name, Lerochol, under both IND 134579 and BLA 761427.

1.2 PRODUCT INFORMATION

The following product information is provided in the prescribing information received on December 16, 2024.[c]

Table 1. Relevant Product Information for Lerochol	
Intended pronunciation:	Leer-O-call
Active ingredient:	lerodalcibep-xxxx
Indication:	(b) (4)
Dosage Form:	injection
Strength:	300 mg/1.2 mL (250 mg/mL)
Route of administration:	subcutaneous

[b] Proprietary Name Safety Summary for Lerochol. (b) (4) 2024 SEP 13. Available from: \\CDSESUB1\EVSPROD\ind134579\0074\m1\us\118-proprietary-names\proprietary-name-safety-summary-for-lerochol.pdf

[c] Proposed prescribing information for Leroc hol. Cincinnati (OH); LIB Therapeutics; 2024 DEC 12. Available from: \\CDSESUB1\EVSPROD\bla761427\0001\m1\us\114-labeling\draft\labeling\proposed.docx

Table 1. Relevant Product Information for Lerochol	
Dose and frequency:	300 mg (1 injection) once a month
How Supplied:	1 Prefilled syringe per carton
Storage:	(b) (4) Store refrigerated at 2° to 8°C (36° to 46°F) in the original carton to protect from light. Do not freeze. Do not shake. (b) (4) LEROCHOL (b) (4) be kept at room temperature (up to 25°C (77°F)) in the original carton; (b) (4) must be used within (b) (4) months. If not used within the (b) (4) months, discard LEROCHOL.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Lerochol 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 Lerochol. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Lerochol.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

LIB did not provide a derivation or intended meaning for the proposed proprietary name, Lerochol, in their submission. This proprietary name is comprised of a single word that contains the letter string "-er-", which is a medical abbreviation for "extended release". We determined that the location of the letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, we do not object to the inclusion of the letter string "-er-" in the prefix/infix of the proposed proprietary name. Additionally, the proposed proprietary name Lerochol ends with the letter string "-chol" which evokes the word "cholesterol". With respect to the letter string '-chol', we note that the product is indicated as (b) (4)

[d] USAN stem search conducted on December 9, 2024 and rechecked on January 2, 2025.g

[redacted] (b) (4) thus would not lead to confusion in this case. Beyond these abbreviations, we note that Lerochol does not contain any additional components (i.e., route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL AREVIEW

The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Lerochol at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-eight (n=98) practitioners participated in DMEPA's prescription simulation studies for Lerochol. One respondent in the verbal prescription study commented that Lerochol "*could be confused with Lyrica*." We further evaluated the name pair Lerochol and Lyrica and determined that the risk for name confusion is adequately minimized (Appendix E).

Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[e] identified 213 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, FDA Prescription Simulation Study, and (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	8
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	187
Low similarity name pair: combined match percentage score ≤54%	19

[e] POCA search conducted on December 9, 2024 in version 5.9.

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

Our analysis of the 214 names contained in Table 2 determined none of the names will pose a risk for confusion with Lerochol as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 13, 2025, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Lerochol, is conditionally acceptable.

3.1 COMMENTS TO LIB THERAPEUTICS

We have completed our review of the proposed proprietary name, Lerochol, 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 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.[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 (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[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, 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 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?		

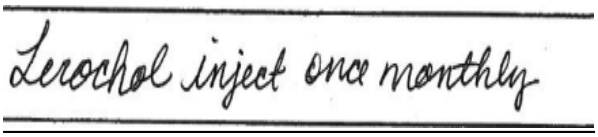
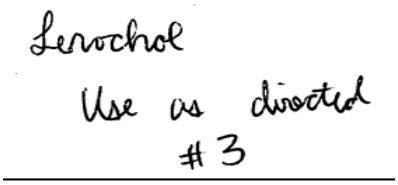
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**	
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td></td><td colspan="2">To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:
Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.
Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
Is there different number or placement of cross-stroke or dotted letters present in the names?
Do the infixes of the name appear dissimilar when scripted?
Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
Do the names have different number of syllables?
Do the names have different syllabic stresses?
Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

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. Lerochol Study (Conducted on 10/22/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Lerochol Use as directed #3
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Lerochol	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Lerochol People Received Study: 187 People Responded: 98					
Total	28	22	24	24	98
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
KEROCHAL	1	0	0	0	1
LEAROCALL	0	0	1	0	1
LECOCHOL	1	0	0	0	1
LEEROCAL	0	0	1	0	1
LENOCHOL	0	1	0	0	1
LEOROCALL	0	0	1	0	1
LEROCAL	0	0	1	0	1
LEROCALL	0	0	2	0	2
LEROCHAOL	1	0	0	0	1
LEROCHOL	24	18	1	24	67
LEROCJOL	1	0	0	0	1
LEROCOL	0	0	1	0	1
LEROKOL	0	0	1	0	1

LEVOCHOL	0	2	0	0	2
LIEROCOL	0	0	1	0	1
LIROCALL	0	0	2	0	2
LIROCOL	0	0	2	0	2
LOROCHOL	0	1	0	0	1
LYROCAL	0	0	2	0	2
LYROCALL	0	0	1	0	1
LYROCHOL	0	0	1	0	1
LYROCOL	0	0	4	0	4
LYROKALL	0	0	1	0	1
RIURACOL	0	0	1	0	1

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

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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.	Lerochol	100	This name is the subject of this review.
2.	Labrocol	80	International product marketed in United Kingdom.
3.	Sclerosol	76	Orthographically, the names start with different letters (L versus S). Sclerosol has an upstroke letter 'l' in the third position whereas Lerochol has an upstroke letter 'h' in the sixth position, providing the names with some difference in shape. Phonetically, the first syllables (Leer vs. Sclee) provide some differences. Sclerosol is available as an intrapleural aerosol used during thoracoscopy or open thoracotomy to prevent recurrence of malignant pleural effusions in symptomatic patients and dosed at 4 to 8 grams once whereas Lerochol is available as a subcutaneous injection and dosed as one injection (300 mg) once a month. The dose of Sclerosol would need to be specified on the prescription or medication order and there are no dosage overlaps. Additionally, there is no overlap in dosage form, route of administration, or frequency of administration (if included on a prescription/medication order).

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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.
			When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
4.	Allersol	72	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Chloracol	72	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
6.	Clearsol	72	International product marketed in United Kingdom.
7.	Ferocyl	72	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Letrozole	70	Orthographically, Letrozole has a cross stroke, upstroke letter “t” in the third position whereas Lerochol has an upstroke letter ‘h’ in the sixth position, providing the names with some difference in shape. Phonetically, the endings of first syllables (Leer vs. Let), the beginning of second syllables (O vs. ro), and the beginning of the third syllables (call vs. zole) provide sufficient phonetic differences. Letrozole is available as an oral tablet and dosed daily for breast cancer in post-

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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.
			menopausal women whereas Lerochol is available as a subcutaneous injection and dosed as once a month. There is no overlap in dosage form, route of administration, or frequency of administration (if included on a prescription/medication order). When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

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-N/A

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

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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.	Aller-Chlor	69	This name pair has sufficient orthographic and phonetic differences.
2.	Lidothol	68	This name pair has sufficient orthographic and phonetic differences.
3.	Ferosul	68	This name pair has sufficient orthographic and phonetic differences.
4.	Allersol A	68	This name pair has sufficient orthographic and phonetic differences.
5.	Cerovel	68	This name pair has sufficient orthographic and phonetic differences.
6.	Xaracoll	67	This name pair has sufficient orthographic and phonetic differences.
7.	Spherusol	66	This name pair has sufficient orthographic and phonetic differences.
8.	Welchol	66	This name pair has sufficient orthographic and phonetic differences.
9.	Lioresal	65	This name pair has sufficient orthographic and phonetic differences.
10.	Florical	65	This name pair has sufficient orthographic and phonetic differences.
11.	Cheracol D	65	This name pair has sufficient orthographic and phonetic differences.
12.	Lavacol	64	This name pair has sufficient orthographic and phonetic differences.
13.	Lerosett	64	Orthographically, Lerochol has an upstroke letter “h” in the sixth position

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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
			which is absent in Lerosett and Lerosett has two cross stroke, upstroke letter "t" in its seventh and eighth positions whereas Lerochol only has an upstroke 'l' in the eighth position, providing the names with some differences in shape. Phonetically, the third syllables (chol vs. sett) provide some phonetic differences. Lerosett is available as a topical gel for treatment of acne. It is intended to be administered as a thin layer applied 2 to 3 times daily whereas Lerochol is available as a subcutaneous injection and administered as one injection (300 mg) once a month. There is no overlap in dose, dosage form, route of administration, or frequency of administration (if included on a prescription/medication order). When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
14.	Seroquel	64	This name pair has sufficient orthographic and phonetic differences.
15.	Aller-Cort	64	This name pair has sufficient orthographic and phonetic differences.
16.	Allercon	63	This name pair has sufficient orthographic and phonetic differences.
17.	Levoxyl	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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
18.	Claripel	60	This name pair has sufficient orthographic and phonetic differences.
19.	Lopressor	60	This name pair has sufficient orthographic and phonetic differences.
20.	Miochol (root name of Miochol E)	60	This name pair has sufficient orthographic and phonetic differences.
21.	Ferocon	60	This name pair has sufficient orthographic and phonetic differences.
22.	Pravachol	60	This name pair has sufficient orthographic and phonetic differences.
23.	Levorphanol	59	This name pair has sufficient orthographic and phonetic differences.
24.	Lorcet-Hd	59	This name pair has sufficient orthographic and phonetic differences.
25.	Calderol	59	This name pair has sufficient orthographic and phonetic differences.
26.	Larotid	58	This name pair has sufficient orthographic and phonetic differences.
27.	Sterogyl	58	This name pair has sufficient orthographic and phonetic differences.
28.	Lidocort	58	This name pair has sufficient orthographic and phonetic differences.
29.	Aller-Flo	58	This name pair has sufficient orthographic and phonetic differences.
30.	Peroxyl	58	This name pair has sufficient orthographic and phonetic differences.
31.	Levophed	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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
32.	Lo-Trol	58	This name pair has sufficient orthographic and phonetic differences.
33.	Locholest	58	This name pair has sufficient orthographic and phonetic differences.
34.	Lozol	57	This name pair has sufficient orthographic and phonetic differences.
35.	Dr. Scholl's	57	This name pair has sufficient orthographic and phonetic differences.
36.	Lidotral	56	This name pair has sufficient orthographic and phonetic differences.
37.	Lipiodol	56	This name pair has sufficient orthographic and phonetic differences.
38.	Superoxol	56	This name pair has sufficient orthographic and phonetic differences.
39.	Lorcet	56	This name pair has sufficient orthographic and phonetic differences.
40.	Allerest 12 Hour	56	This name pair has sufficient orthographic and phonetic differences.
41.	Hydrocil	56	This name pair has sufficient orthographic and phonetic differences.
42.	Lodoco	56	This name pair has sufficient orthographic and phonetic differences.
43.	Lescol Xl	56	This name pair has sufficient orthographic and phonetic differences.
44.	Cefiderocol	56	This name pair has sufficient orthographic and phonetic differences.
45.	Lactitol	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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
46.	Lomotil	55	This name pair has sufficient orthographic and phonetic differences.
47.	Miochol-E	55	This name pair has sufficient orthographic and phonetic differences.
48.	Lyrica	50	This name pair has sufficient orthographic differences. Phonetically, the second syllables ('O' vs. 'i') and the endings of third syllables ('call' vs. 'kah") offer some differences. Furthermore, Lerochol is available as a subcutaneous injection once monthly and is indicated (b) (4) [redacted] Lyrica is available as an oral capsule and oral solution administered 2 or 3 times a day depending on the indication and population for neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, adjunctive therapy for the treatment of

No.	Proposed name: Lerochol Pronunciation: Leer-O-call Established name: lerodalcibep-xxxx Dosage form: injection Strength(s): 300 mg/1.2 mL (250 mg/mL) Dosage: 1 injection once a month	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
			partial-onset seizures in patients 1 month of age and older, fibromyalgia, neuropathic pain associated with spinal cord injury. Additionally, the dosage forms differ (injection vs. oral capsule/oral solution) as well as the frequency of administration (once a month vs. 2 or 3 times a day), and the dosage form and frequency of administration would need to be specified on a prescription/medication order for Lyrica. Additionally, there is no overlap in the route of administration (subcutaneous vs. oral) if included on a prescription/medication order. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

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

No.	Name	POCA Score (%)
1.	E Pherol	54
2.	Cleocin Hcl	54
3.	Percolone	53
4.	Demerol Hcl	53
5.	Oleyl Alcohol	52
6.	Broncholate	52
7.	P-Chloro-M-Cresol	52

No.	Name	POCA Score (%)
8.	Ketochlor	52
9.	Cholesterol	51
10.	Virasal	50
11.	Provocholine	50
12.	Dehydrocholate	50
13.	Sochlor	50
14.	Mecholyl	49
15.	Tocopherol	49
16.	Econochlor	48
17.	Hectorol	47
18.	De-chlor HC	44
19.	Choleth-20	42

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.	Lescol	69	Brand discontinued with no generic equivalents available. NDA 020261 withdrawn FR effective May 1, 2019.
2.	Fenochol	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Levatol	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Murocoll 2	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Celectol	64	International product marketed in France, the United Kingdom, and Czech Republic.
6.	Entrocel	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	(b) (4) ***	64	Proposed proprietary name withdrawn by the Applicant. NDA 212895 approved under the proprietary name Conjupri.
8.	Lorelco	64	Brand discontinued with no generic equivalents available. NDA 017535 withdrawn FR effective June 4, 2004.

No.	Name	POCA Score (%)	Failure preventions
9.	Sclero seal	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Creosol	63	Product is not a drug. It is a chemical compound which is a component of creosote.
11.	Chlorocresol	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
12.	Murocel	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Antrocol	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Reproterol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Carbachol	60	Brand discontinued with no generic equivalents available. ANDA 070292 withdrawn FR effective October 21, 1993.
16.	Roccal	60	International product formerly marketed in Ireland.
17.	Roc-cal	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Chlorothymol	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Ledercort	59	International product marketed in Japan, Sweden, Belgium, Switzerland, Netherlands, Norway, United Kingdom, Italy, South Africa, and Spain.
20.	Nerolidol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Lemon Oil	58	This product is not a drug. Lemon oil used in various products to eliminate odors and to infuse aroma.
22.	Leritine	58	Brand discontinued with no generic equivalents available. NDA 010520 withdrawn FR effective 3/20/2000.
23.	Lodocort	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	Lactocal	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	Luprostiol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
26.	Vanachol	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
27.	Lavoclen	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
28.	Bellergal	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
29.	Levomenthol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	(b) (4)***	56	Proposed proprietary name for IND 124947 found unacceptable by DMEPA (2018-27985847; May 10, 2019). NDA 212895 approved under the proprietary name Conjupri.
31.	Loceryl	56	International product marketed in Argentina, Austrailia, Belgium, Brazil, Chile, China, Denmark, Finland, France, Germany, Greece, Hong Kong, India, Mexico, Norway, Poland, Russia, South Africa, Sweden, Switzerland, Thailand, United Kingdom, Venezuela, New Zealand, Israel, and Turkey.
32.	Cedrol	56	International product formerly marketed in Spain.
33.	Orthocresol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Lergoban	55	International product marketed in United Kingdom.
35.	Sobrerol	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
36.	Bronchodil	55	International product marketed in United Kingdom.
37.	Larodopa	55	Brand discontinued with no generic equivalents available. NDA 016912 withdrawn FR effective June 4, 2004.
38.	Nerol	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	(b) (4)***	55	Proposed CBER proprietary name (b) (4)*** found unacceptable on January 30, 2017, under BLA 125640. BLA 125640 approved under proprietary name VistaSeal.

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.	Chlorophyll	66
2.	Dermacool	66
3.	Percutol	66
4.	Thoracol	66
5.	Irofol	64
6.	Zeranol	64
7.	Berkolol	62
8.	Dermatol 10	62
9.	Ery-Sol	62
10.	Keratol	62
11.	Keratol 40	62
12.	Mertodol	62
13.	Metrozol	62
14.	Perisol	62
15.	Terazol 3	62
16.	Terazol 7	62
17.	Sevosol	61
18.	Sevredol	61
19.	Tegretol	61
20.	Clinosol 15%	60
21.	Fer-In-Sol	60
22.	Iron Sol	60
23.	Mersol	60
24.	Renocal	60
25.	Renocal-76	60
26.	Reversol	60
27.	Sloprolol	60
28.	Tetrachel	60

[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

No.	Name	POCA Score (%)
29.	Urodol	60
30.	Vermidol	60
31.	Alevazol	59
32.	Celiprolol	59
33.	Clofoctol	59
34.	Fluro-Ethyl	59
35.	Prosol	59
36.	Baratol	58
37.	Calteridol	58
38.	Carbopol 981	58
39.	Cerefolin	58
40.	Charcoal	58
41.	Chlor-Mal	58
42.	Chloroform	58
43.	Circanol	58
44.	Citrucel	58
45.	Clearasil	58
46.	Clorotekal	58
47.	Ferrogels	58
48.	Floropryl	58
49.	Glaucol	58
50.	Helicosol	58
51.	Hyprosol	58
52.	Ioversol	58
53.	Pharbetol	58
54.	Probucol	58
55.	Regonol	58
56.	Revitol	58
57.	Sarisol	58
58.	Tearisol	58
59.	Theosol-80	58
60.	Durezol	57

No.	Name	POCA Score (%)
61.	Rebetol	57
62.	Slentrol	57
63.	Spironol	57
64.	Thera-Sal	57
65.	Alacol	56
66.	Chlor-Al Rel	56
67.	Chlorothen	56
68.	Clevecord	56
69.	Cloprednol	56
70.	Clorophene	56
71.	Cresol	56
72.	Delzicol	56
73.	Dermacool Hc	56
74.	Erythritol	56
75.	Farnesol	56
76.	Feosol	56
77.	Fluosol	56
78.	Frusol	56
79.	Garasol	56
80.	Keratol Hc	56
81.	Klor-Con	56
82.	Klor-Con 10	56
83.	Klor-Con 8	56
84.	Klor-Con/25	56
85.	Metrogel	56
86.	Microsul	56
87.	Mylocel	56
88.	Rectasol	56
89.	Redisol	56
90.	Senosol	56
91.	Vaprisol	56
92.	Veracolate	56

No.	Name	POCA Score (%)
93.	Viranol	56
94.	Bedranol	55
95.	Bronchitol	55
96.	Cebatrol	55
97.	Corticool	55
98.	Dermol HC	55
99.	Earsol-HC	55
100.	Neosol	55

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/s/

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