CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215040Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	October 19, 2023
Application Type and Number:	Application Type Number/S-000
Product Name and Strength:	Legubeti (established name) for oral solution, 500 mg and 2.5 grams
Product Type:	Single Ingredient Product
Rx or OTC:	Choose an item
Applicant/Sponsor Name:	Galephar Pharmaceutical Research Inc. (Galephar)
PNR ID #:	2023-1044725312
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Legubeti, which was found conditionally acceptable under NDA 215040 on December 21, 2022.[a]

2 REGULATORY HISTORY

Galephar previously submitted the proposed proprietary name, [redacted] (b) (4) on August 16, 2022. However, under NDA 215040 on September 19, 2022, we found the name, [redacted] (b) (4) unacceptable because it would misbrand the proposed product.[b]

Subsequently, Galephar submitted the proposed proprietary name, Legubeti, for review on October 7, 2022, under NDA 215040. We found the proposed name, Legubeti, conditionally acceptable on December 21, 2022; however, the Application received a complete response (CR) on May 5, 2023, due to clinical and regulatory deficiencies.

Thus, Galephar submitted the name, Legubeti, under NDA 215040 for re-review on August 14, 2023 with their response to the May 5, 2023, CR letter. We note that there is a change in the established name from "*acetylcysteine lysine*" to "*acetylcysteine*" for Application Type Number/S-000. All other product characteristics remain the same.

3 METHODS AND DISCUSSION

3.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Legubeti would not misbrand the proposed product. However, OPDP provided a comment noting *"Legubeti sounds like Leqembi."* We previously assessed the name pair, Legubeti *versus* Leqembi and determined there would be minimal risk of name confusion.[c] The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the misbranding findings of OPDP's assessment for Legubeti. The Division of Ophthalmology (DO) concurred with the misbranding findings of OPDP's assessment for Legubeti.

3.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in established name from "*acetylcysteine lysine*" to "*acetylcysteine*." Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Legubeti.

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[a] Getahun, S. Proprietary Name Review for Legubeti (NDA 215040). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 DEC 21. PNR ID No. 2022-1044724795.

[b] Getahun, S. Proprietary Name Review for [redacted] (b) (4) (NDA 215040). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 SEP 19. PNR ID No. 2022-1044724711.

[c] Getahun, S. Proprietary Name Review for Legubeti (NDA 215040). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 DEC 21. PNR ID No. 2022-1044724795.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The August 31, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Legubeti.

3.3 COMMUNICATION OF DMEPA'S DETERMINATION

On October 19, 2023, we communicated our determination to the Division of Ophthalmology (DO).

4 CONCLUSION

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

If you have any questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

4.1 COMMENTS TO GALEPHAR PHARMACEUTICAL RESEARCH INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 14, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

5 REFERENCE

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

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/

SOFANIT N GETAHUN
10/19/2023 12:54:04 PM

VALERIE S VAUGHAN
10/19/2023 03:57:20 PM

MISHALE P MISTRY
10/20/2023 02:25:33 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 21, 2022
Application Type and Number:	NDA 215040
Product Name and Strength:	Legubeti (acetylcysteine lysine) powder for oral solution, 500 mg and 2.5 grams
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Galephar Pharmaceutical Research Inc. (Galephar)
PNR ID #:	2022-1044724795
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD., BCPS.
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD., MPH

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Galephar previously submitted the proposed proprietary name, [redacted] (b) (4) on August 16, 2022. However, under NDA 215040 on September 19, 2022, we found the name, [redacted] (b) (4) unacceptable because it would misbrand the proposed product.[a]

Thus, Galephar submitted the name, Legubeti, for review on October 7, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 7, 2022.

- Intended Pronunciation: */leg-u-beti/*
- Active Ingredient: acetylcysteine lysine
- Indication of Use: indicated as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen. It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of ingestion.
- Route of Administration: Oral
- Dosage Form: powder for oral solution
- Strength: 500 mg and 2.5 grams
- Dose and Frequency:
    - Recommended Adult and Pediatric Dosage
        - Loading dose: 140 mg/kg
        - Maintenance doses: 70 mg/kg repeated every 4 hours for total of 17 doses
- How Supplied:
    - 500 mg sachets printed with “Lot Number and Expiration Date” on one side. Each carton containing 10 or 20 sachets
        - NDC 66277-319-10: boxes of 10 sachets.
        - NDC 66277-290-20: boxes of 20 sachets.

[a] Getahun, S. Proprietary Name Review for [redacted] (b) (4) (NDA 215040). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 SEP 19. PNR ID No. 2022-1044724711.

- 2.5 grams sachets printed with “Lot Number and Expiration Date” on one side. Each carton containing 10 or 20 sachets
    - NDC 66277-320-10: boxes10 sachets.
    - NDC 66277-291-20: boxes 20 sachets.

- Storage: Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature.] Protect from moisture. Store in original package until use.
- Reference Product: Mucomyst (acetylcysteine) NDA 013601

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Legubeti 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 Legubeti. The Division of Hepatology and Nutrition (DHN) concurred with the findings of OPDP’s assessment for Legubeti.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Galephar did not provide a derivation or intended meaning for the proposed proprietary name, Legubeti, in their submission. This proprietary name is comprised of a single word that contains the letter string ‘-et-,’ a medical abbreviation for the route of administration, endotracheal tube, which may be used on a prescription to direct that the product is to be administered via the endotracheal tube. In some circumstances, the incorporation of medical abbreviations in the proprietary names can inadvertently be a source of error. For more information see, *Best Practices in Developing Proprietary Names for Human Prescription Drug Products.*[c] Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the incorporation of the abbreviation, ‘-et-’ is unlikely to be separated in a

[b] USAN stem search conducted on November 16, 2022.

[c] Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products. 2020. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents

manner that would lead to confusion in this case. Thus, in this case, we do not object to the inclusion of the letter string '-et-' in the proposed proprietary name.

2.2.3 Comments from Other Review Disciplines at Initial Review

On October 28, 2022, the Division of Hepatology and Nutrition (DHN) did not forward any comments or concerns relating to Legubeti at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred (100) practitioners participated in DMEPA's prescription studies for Legubeti. One participant in the voice prescription simulation misinterpreted the proposed propriety name Legubeti as the currently marketed product "Amiodarone." The participant's reason for interpreting the proposed proprietary name as Amiodarone is *"Best guess as no other medications seem to fit."* Nonetheless, we evaluated the name pair, "Legubeti" and "Amiodarone" further in Appendix F.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 43 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. 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%	37
Low similarity name pair: combined match percentage score ≤54%	6

[d] POCA search conducted on October 14, 2022 in version 5.0.

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

Our analysis of the 44 names contained in Table 1 determined none of the names will pose a risk for confusion with Legubeti as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On December 21, 2022, DMEPA 1 communicated our determination to the Division of Hepatology and Nutrition (DHN).

3 CONCLUSION

The proposed proprietary name, Legubeti, is conditionally acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

3.1 COMMENTS TO GALEPHAR PHARMACEUTICAL RESEARCH INC.

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

If any of the proposed product characteristics as stated in your submission, received on October 7, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

[e] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

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 staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

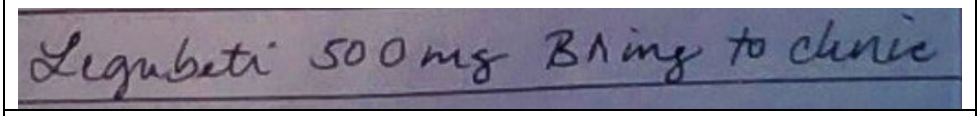
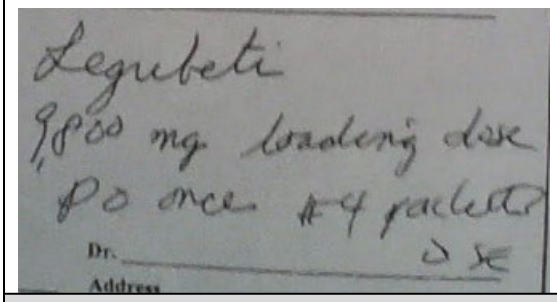
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Legubeti Study (Conducted on October 26, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** **Legubeti**	Legubeti 9,800 mg loading dose by mouth once. Dispense 4 packets

FDA Prescription Simulation Responses (Aggregate Report)

264 People Received Study

100 People Responded

Study Name: Legubeti

Total	**24**	**28**	**25**	**23**
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
AMIODARONE	0	0	1	0	1
LACUBIDI	0	0	1	0	1
LAGOBYDEE	0	0	1	0	1
LAGOPODE	0	0	1	0	1
LAGUBEDEE	0	0	1	0	1
LAGUBIDI	0	0	1	0	1

LAGUBIDY	0	0	5	0	5
LAGUBITY	0	0	3	0	3
LAGUBODY	0	0	1	0	1
LEGABETI	3	0	0	0	3
LEGNBATI	1	0	0	0	1
LEGREBETI	0	0	0	9	9
LEGRIBETI	0	0	0	4	4
LEGUBATI	2	0	0	0	2
LEGUBATR	2	0	0	0	2
LEGUBATRI	1	0	0	0	1
LEGUBETA	1	0	0	0	1
LEGUBETI	8	28	1	9	46
LEGUBETI 500 MG	1	0	0	0	1
LEGUBETRI	2	0	0	0	2
LEGUBIDI	0	0	1	0	1
LEGUBIDY	0	0	3	0	3
LEGUBITY	0	0	1	0	1
LEGUVITY	0	0	1	0	1
LEQUBETI	0	0	0	1	1
LEQUIBETI	1	0	0	0	1
LIGUBETI	1	0	0	0	1
LIGUVITY	0	0	1	0	1
LUGUBITY	0	0	1	0	1
MAGUBIDY	0	0	1	0	1
XXX	1	0	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Legubeti **Established name:** acetylcysteine lysine **Dosage form:** powder for oral solution **Strength(s):** 500 mg and 2.5 grams **Usual Dose:** 3,500 mg every 4 hours by mouth for total of 17 doses	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.	Legubeti	100	Name is 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.	Liquibid	62
2.	Lytgobi	58
3.	Liptruzet	56
4.	Liquibid DR	56
5.	Levonest	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:** Legubeti **Established name:** acetylcysteine lysine **Dosage form:** powder for oral solution **Strength(s):** 500 mg and 2.5 grams **Usual Dose:** 3,500 mg every 4 hours by mouth for total of 17 doses	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.	Lexette	64	This name pair has sufficient orthographic and phonetic differences.
2.	Leqembi***	62	Orthographically, the infixes/suffixes (-ube- *versus* -em-) provide the name pair some orthographic difference. Phonetically, the second syllables 'u' *versus* 'kem' provide the pair sufficient

No.	**Proposed name:** Legubeti **Established name:** acetylcysteine lysine **Dosage form:** powder for oral solution **Strength(s):** 500 mg and 2.5 grams **Usual Dose:** 3,500 mg every 4 hours by mouth for total of 17 doses	**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**
			phonetic difference. Additionally, Legubeti contains an extra syllable. In addition to orthographic and phonetic differences, there is no overlap in route of administration (oral *versus* intravenous) or dosage form (powder for oral solution *versus* injection), if included on a prescription order. Additionally, there is no overlap in dose (140 mg/kg loading dose and 70 mg/kg maintenance dose *versus* 10 mg/kg/dose), which may help to further minimize the risk of error. When all the forementioned mitigations are considered in totality, the risk of name confusion is adequately minimized in this case.
3.	Leustatin	58	This name pair has sufficient orthographic and phonetic differences.
4.	Levbid	58	This name pair has sufficient orthographic and phonetic differences.
5.	Leukotac***	56	This name pair has sufficient orthographic and phonetic differences.
6.	Levolet	56	This name pair has sufficient orthographic and phonetic differences.
7.	Liquimat	56	This name pair has sufficient orthographic and phonetic differences.
8.	Lucentis	56	This name pair has sufficient orthographic and phonetic differences.
9.	Ludent	56	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.	Albiglutide	53
2.	Levodopa	52
3.	Ubretid	51
4.	Betulin	50
5.	Blue Gel	46
6.	Amiodarone	16

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.	Libetist	65	International product formerly marketed in the United Kingdom.
2.	Leg-Gesic	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Liquicet	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Regu-Mate	61	Veterinary product.
5.	Glucamet	60	International product formerly marketed in the United Kingdom.
6.	Ibumetin	60	International product formerly marketed in Austria, Denmark, United Kingdom, Norway, Sweden, and Netherlands
7.	Lergoban	60	International product formerly marketed in the United Kingdom.
8.	Liquibid-D	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	Lutetium	60	Product is not a drug it is a radiopharmaceutical product. Additionally, it is a homeopathic agent.
10.	Legacy	58	Veterinary product.
11.	(b) (4)	58	Proposed proprietary name for IND 138178 found to be acceptable (OSE # 2021-1044723863); however, the name was withdrawn by the Applicant on May 03, 2022. Alternate name Columvi*** is currently under review.

No.	Name	POCA Score (%)	Failure preventions
12.	Luviset 360	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Equi-Bute	56	Veterinary product.
14.	(b) (4)	56	Proposed proprietary name withdrawn by the Applicant. NDA 213227 approved under the proprietary name, Detectnet.
15.	Lagesic	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Leventa	56	Veterinary product.
17.	(b) (4)	56	Proposed proprietary name for IND 124813 and NDA 215430 found unacceptable by DMEPA on April 6, 2021 (OSE# 2021-1044723772 and 2021-1044723822). NDA 215430 approved under the proprietary name Auvelity.
18.	Iletin Ii	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	(b) (4) ***	55	Proposed proprietary name for IND (b) (4) found unacceptable by CBER because it would misbrand the proposed product. IND (b) (4) is pending, and no new names have been submitted.
20.	Stilbetin	55	Brand discontinued with no generic equivalents available. NDA 004056 withdrawn FR effective 09/13/2000.

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

No.	Name	POCA Score (%)
1.	Eliglustat	56
2.	Rexulti	56
3.	Tegsedi	55

[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

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	September 19, 2022
Application Type and Number:	NDA 215040
Product Name and Strength:	(b) (4) (acetylcysteine lysine) powder for oral solution, 500 mg and 2.5 grams
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Galephar Pharmaceutical Research Inc. (Galephar)
PNR ID #:	2022-1044724711
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD., BCPS.
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD., MPH

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