# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761269Orig1s000

# PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

| | |
|---|---|
| **Date of This Review:** | 3/24/2022 |
| **Responsible OND Division:** | Division of Neurology 1 (DN 1) |
| **Application Type and Number:** | BLA 761269 |
| **Product Name and Strength:** | Leqembi (lecanemab-irmb) injection<br>200 mg/2 mL and 500 mg/5 mL (100 mg/mL) |
| **Product Type:** | Single Ingredient Product |
| **Applicant/Sponsor Name:** | Eisai Inc. (Eisai) |
| **FDA Received Date:** | December 14, 2021 |
| **Nexus NPNS ID #:** | 2021-68 |
| **DMAMES Biologics Suffix Specialist:** | Carlos M Mena-Grillasca, BS Pharm |
| **DMEPA 2 Director:** | Danielle Harris, PharmD |

## 1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Eisai for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761269.

## 2 ASSESSMENT OF THE NONPROPRIETARY NAME

On December 14, 2021, Eisai submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Eisai also provided findings from an external study conducted by (b) (4), evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Eisai:

| Table 1. Suffixes submitted by Eisai*** | |
|---|---|
| 1. | irmb |
| 2. | (b) (4) |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |
| 9. | |
| 10. | |

[a] Request for Comments and Advice – Non-Proprietary Names – Lecanemab Proposed Suffix BLA 761269. Woodcliff Lake (NJ): Eisai Inc.; 2021 Dec 14. Available from: \\CDSESUB1\evsprod\bla761269\0002\m1\us\118-non-proprietary-names.pdf

[b] Data Summary for Proposed Suffixes BLA 761269. (b) (4); 2021 Dec 3. Available from: \\CDSESUB1\evsprod\bla761269\0002\m1\us\118-non-proprietary-names.pdf

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

### 2.1 lecanemab-irmb

Eisai's first proposed suffix, -irmb, is comprised of 4 distinct letters. We note that the letters 'ir' in the suffix represent the medical abbreviation for 'immediate release'. We considered whether the inclusion of the letters 'ir' 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 -irmb, 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 2 ANALYSIS

These findings were shared with OPDP. On March 22, 2022, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMAMES also communicated our findings to the Division of Neurology 1 (DN 1) on March 24, 2022.

## 4 CONCLUSION

We find Eisai's proposed suffix -irmb acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to lecanemab-irmb. DMEPA 2 will communicate our findings to the Applicant via letter.

### 4.1 Recommendations for Eisai Inc.

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

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

suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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

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/s/

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CARLOS M MENA-GRILLASCA
03/24/2022 10:56:36 AM

DANIELLE M HARRIS
03/24/2022 03:09:22 PM

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

| | |
|---|---|
| **Date of This Review:** | February 16, 2022 |
| **Application Type and Number:** | BLA 761269 |
| **Product Name and Strength:** | Leqembi (lecanemab-xxxx)[a] Injection, 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL) |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Eisai Inc. (Eisai) |
| **PNR ID #:** | 2021-1044724330 |
| **DMEPA 2 Safety Evaluator:** | Beverly Weitzman, PharmD |
| **DMEPA 2 Team Leader (Acting):** | Stephanie DeGraw, PharmD |
| **DMEPA 2 Director:** | Danielle Harris, PharmD |

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

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Leqembi, 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. Eisai submitted an external name study, conducted by [redacted], for this proposed proprietary name.

## 1.1 REGULATORY HISTORY

Eisai previously submitted the proposed proprietary name, [redacted]*** under IND 105081 on November 12, 2020. However, we found the name, [redacted]*** unacceptable due to misbranding concerns on December 9, 2020.[b]

Subsequently, Eisai submitted the proposed proprietary name, [redacted]*** under IND 105081. We found the proposed name [redacted]*** conditionally acceptable on July 20, 2021.[c] However, the Sponsor withdrew the name [redacted]*** on December 20, 2021.[d]

Thus, Eisai submitted the name, Leqembi, for review under BLA 761269 on December 14, 2021.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 14, 2021.

- Intended Pronunciation: leh kem' bee
- Nonproprietary Name: lecanemab-xxxx
- Indication of Use: For the treatment of Early Alzheimer's Disease (mild cognitive impairment due to AD and mild AD dementia, with confirmed amyloid pathology).
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)
- Dose and Frequency: The recommended starting and maintenance dose is 10 mg/kg/dose every 2 weeks. Maximum daily dose in 24 hours: 10 mg/kg/dose.
- How Supplied: 500 mg/5 mL (100 mg/mL) single-dose vial (with white flip cap)
  200 mg/2 mL (100 mg/mL) single-dose vial (with dark grey flip cap)

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[b] Kalonia, K. Proprietary Name Review for [redacted]*** (IND 105081). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2020 DEC 9. Panorama No. 2020-43909644.

[c] Weitzman, B. Proprietary Name Review for [redacted]*** (IND 105081). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 JUL 20. Panorama No. 2021-104472377.

[d] Withdrawal of Proprietary name review for [redacted]*** (IND 105081) available from docuBridge via: \\CDSESUB1\evsprod\ind105081\0187\m1\us\cover.pdf

- Storage: Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. After dilution, immediate use is recommended. If not administered immediately, the product may be stored up to (b) (4) hours at a refrigerated temperature (2°C to 8°C [36°F to 46°F]), or at room temperature up to 30°C (86°F) for up to (b) (4) hours. Do not freeze or shake vials.
- Reference Listed Drug/Reference Product: N/A

# 2 RESULTS

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

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Leqembi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Leqembi. However, the Division of Neurology 1 (DN 1) did not provide comments regarding OPDP's assessment.

## 2.2 SAFETY ASSESSMENT

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

### *2.2.1 United States Adopted Names (USAN) Search*

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

### *2.2.2 Components of the Proposed Proprietary Name*

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

### *2.2.3 Comments from Other Review Disciplines at Initial Review*

The Division of Neurology 1 (DN 1) did not provide comments regarding Leqembi at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

One hundred and six practitioners participated in DMEPA's prescription studies for Leqembi. 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.

[e] USAN stem search conducted on December 16, 2021.

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

Our POCA search[f] identified 25 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 (b) (4) external 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:<br>combined match percentage score ≥70% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 18 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 6 |

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

Our analysis of the 25 names contained in Table 1 determined none of the names will pose a risk for confusion with Leqembi as described in Appendices C through H.

### *2.2.8 Communication of DMEPA's Determination*

On February 16, 2022, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

## 3 CONCLUSION

The proposed proprietary name, Leqembi, is acceptable.

If you have any questions or need clarifications, please contact Lopa Thambi, OSE project manager, at 301-796-5354.

### 3.1 COMMENTS TO EISAI INC.

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

[f] POCA search conducted on December 16, 2021 in version 4.4.

If any of the proposed product characteristics as stated in your submission, received on December 14, 2021, 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. [g]

[g] 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[h]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

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

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

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

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

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

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

**Table 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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• 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. |

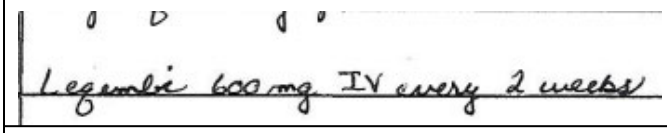
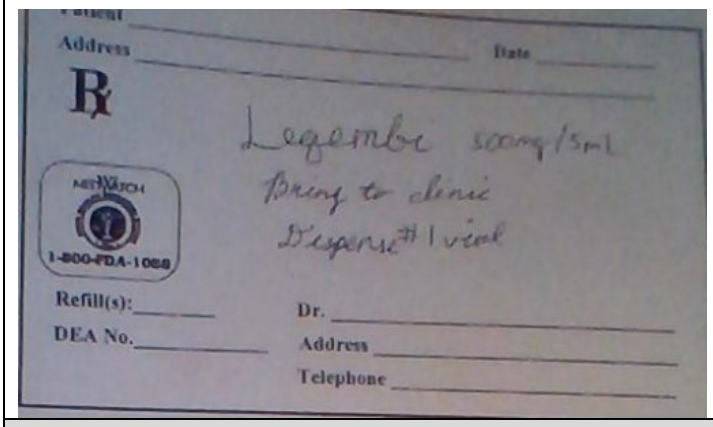
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when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

**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. Leqembi Study (Conducted on December 23, 2021)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Leqembi<br>Bring to clinic<br>Dispense #1 vial |
| Outpatient Prescription:<br>  <br> | |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| Leqembi | |

**FDA Prescription Simulation Responses (Aggregate Report)**

263 People Received Study
106 People Responded

Study Name: Leqembi

| Total | 32 | 28 | 21 | 25 | 106 |
|---|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **CPOE** | **VOICE** | **INPATIENT** | **TOTAL** |
| LAKEMBEE | 0 | 0 | 1 | 0 | 1 |
| LAKEMBI | 0 | 0 | 3 | 0 | 3 |
| LAKEMBY | 0 | 0 | 2 | 0 | 2 |
| LECAMBI | 0 | 0 | 1 | 0 | 1 |
| LECAMBY | 0 | 0 | 1 | 0 | 1 |

| | | | | | |
|---|---|---|---|---|---|
| LEGAMLI | 0 | 0 | 0 | 1 | 1 |
| LEGEMBE | 2 | 0 | 0 | 0 | 2 |
| LEGEMBI | 5 | 0 | 0 | 1 | 6 |
| LEKAMBY | 0 | 0 | 1 | 0 | 1 |
| LEKEMBE | 0 | 0 | 1 | 0 | 1 |
| LEKEMBI | 0 | 0 | 4 | 0 | 4 |
| LEKEMBIE | 0 | 0 | 1 | 0 | 1 |
| LEQEMBE | 1 | 0 | 0 | 0 | 1 |
| LEQEMBI | 22 | 28 | 0 | 19 | 69 |
| LEQEMBI 500MG/5ML | 1 | 0 | 0 | 0 | 1 |
| LEQEMBIC | 0 | 0 | 0 | 2 | 2 |
| LEQEMLI | 0 | 0 | 0 | 1 | 1 |
| LEQUEMBI | 0 | 0 | 0 | 1 | 1 |
| LEZEMBI | 1 | 0 | 0 | 0 | 1 |
| LICAMBI | 0 | 0 | 1 | 0 | 1 |
| MEDCAMBEE | 0 | 0 | 1 | 0 | 1 |
| MYKEMBE | 0 | 0 | 1 | 0 | 1 |
| NAKEMBI | 0 | 0 | 1 | 0 | 1 |
| NIKEMBE | 0 | 0 | 1 | 0 | 1 |
| RICAMPI | 0 | 0 | 1 | 0 | 1 |

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

| No. | **Proposed name:** Leqembi<br>**Established name:** lecanemab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)<br>**Usual Dose:** 10 mg/kg/dose every 2 weeks | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Leqembi | 100 | Proposed proprietary name that 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. | LiceMD | 64 |

**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:** Leqembi<br>**Established name:** lecanemab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)<br>**Usual Dose:** 10 mg/kg/dose every 2 weeks | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | (b) (4) *** | 64 | (b) (4) |

| No. | **Proposed name:** Leqembi<br>**Established name:** lecanemab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)<br>**Usual Dose:** 10 mg/kg/dose every 2 weeks | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| | | | (b) (4) |
| 2. | (b) (4) *** | 62 | |

| No. | **Proposed name:** Leqembi<br>**Established name:** lecanemab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)<br>**Usual Dose:** 10 mg/kg/dose every 2 weeks | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 3. | Levemir | 62 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, Leqembi contains the downstroke letter 'q' in the third position and the upstroke letter 'b' in the sixth position, whereas Levemir does not contain any upstroke or downstroke letters which gives the names different shapes when scripted.<br><br>Phonetically, the offset of the first syllable (leh vs. lev), second syllables (kem' vs. uh) and third syllables (bee vs. meer) sound different when spoken. |
| 4. | Leqvio | 58 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, the Leqembi contains the letter string 'em' in the infix and the upstroke letter 'b' in the suffix, whereas Leqvio contains the letter string 'vi' in the infix and the rounded letter 'o' in the suffix which gives the names different shapes when scripted.<br><br>Phonetically, the second syllables (kem' vs. vee) and third syllables (bee vs. oh) sound different when spoken. |
| 5. | Liquibid | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Liquidbid 1200 | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 7. | Glyxambi | 58 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Leqembi<br>**Established name:** lecanemab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL)<br>**Usual Dose:** 10 mg/kg/dose every 2 weeks | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 8. | Cresemba | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | Lokelma | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 10. | Levbid | 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. | Alkindi<br>Note: Alkindi is the root name of the proprietary name, Alkindi Sprinkle. | 52 |
| 2. | Embelin | 46 |
| 3. | Embeline | 42 |
| 4. | Zokinvy | 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. | (b) (4) *** | 64 | Proposed proprietary name for IND 120651 found unacceptable by DMEPA (OSE# 2020-41433839 dated October 13, 2020). Subsequently, the proposed proprietary name Lunsumio*** was found conditionally acceptable by DMEPA (OSE # 2021-1044723993 dated August 18, 2021) under IND 120651. |
| 2. | Legend | 58 | Veterinary drug product. |
| 3. | Limbrel | 56 | Unapproved medical food product. Applicant withdrew Limbrel products from the marketplace on January 4, 2018. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 4. | Liquibid-D | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 5. | Leventa | 55 | Veterinary drug product. |
| 6. | Blemix | 50 | International product formerly marketed in the United Kingdom. |
| 7. | (b) (4) *** | 48 | Proposed proprietary name for IND 064119 found unacceptable by DMEPA (OSE # 2017-12412628). NDA 210557 approved under the proprietary name, Vyleesi. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Elifemme | 58 |
| 2. | Iletin I | 57 |

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

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**PROPRIETARY NAME REVIEW**

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

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

| | |
|---|---|
| **Date of This Review:** | July 20, 2021 |
| **Application Type and Number:** | IND 105081 |
| **Product Name and Strength:** | (b) (4) (lecanemab) Injection, 100 mg/mL |
| **Total Product Strength:** | 200 mg/2 mL and 500 mg/5 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Eisai Inc. (Eisai) |
| **PNR ID #:** | 2021-104472377 |
| **DMEPA Safety Evaluator:** | Beverly Weitzman, PharmD |
| **DMEPA Team Leader (Acting):** | Celeste Karpow, PharmD, MPH |
| **DMEPA Deputy Director:** | Danielle Harris, PharmD |

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**PROPRIETARY NAME REVIEW**

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

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| | |
|---|---|
| **Date of This Review:** | December 9, 2020 |
| **Application Type and Number:** | IND 105081 |
| **Product Name and Strength:** | (b) (4) (lecanemab) injection, 100 mg/mL |
| **Total Product Strength:** | 200 mg/2 mL, and 500 mg/5 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Eisai Inc. (Eisai) |
| **Panorama #:** | 2020-43909644 |
| **DMEPA Safety Evaluator:** | Justine Kalonia, PharmD |
| **DMEPA Team Leader:** | Briana Rider, PharmD, CPPS |

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