

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761248Orig1s000

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:	10/5/2023
Responsible OND Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	BLA 761248
Product Name and Strength:	Kisunla (donanemab-azbt) injection 350 mg/20 mL (17.5 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Eli Lilly and Company (Lilly)
Nexus NPNS ID #:	2023-184
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -azbt, for BLA 761248, which was found conditionally acceptable on July 29, 2022^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761248.

1.1 Regulatory History

We found the proposed suffix, -azbt, conditionally acceptable for BLA 761248 on July 29, 2022^a. However, BLA 761248 received a Complete Response (CR) letter on January 18, 2023^b. Thus, Lilly submitted a Class 2 Resubmission on June 12, 2023.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the proposed four-letter suffix, -azbt, using the principles described in the applicable guidance^c.

We determined that the proposed suffix -azbt, 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 September 28, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Neurology 1 (DN 1) on October 5, 2023.

^a Mena-Grillasca,C. Nonproprietary Name Suffix Review for donanemab-azbt (BLA 761248). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 Jul 29. Nexus NPNS ID No.: 2022-108.

^b Dunn,B. Complete Response (BLA 761248). Silver Spring (MD): FDA, CDER, OND, ON (US); 2023 Jan 18.

^c Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

4 CONCLUSION

We find the suffix -azbt acceptable and recommend the nonproprietary name donanemab-azbt be used throughout the draft labels and labeling.

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
10/05/2023 11:34:00 AM

CHI-MING TU
10/06/2023 12:07:54 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:	September 1, 2023
Application Type and Number:	BLA 761248
Product Name and Strength:	Kisunla (donanemab-azbt) ^a injection, 350 mg/20 mL (17.5 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Eli Lilly and Company (Eli Lilly)
PNR ID #:	2023-1044725182
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Acting Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

^a The nonproprietary name, donanemab-azbt, was found conditionally acceptable on August 04, 2022.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Kisunla, 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. Eli Lilly submitted an internally conducted name study, for this proposed proprietary name.

1.1 REGULATORY HISTORY

Eli Lilly previously submitted the proposed proprietary name, (b) (4) *** under IND 109157 on August 6, 2021. However, we found the name, (b) (4) *** unacceptable on September 16, 2021 “because, as proposed, it creates a misleading impression regarding the efficacy of the drug”.^b

Therefore, Eli Lilly submitted Kisunla under IND 109157 and BLA 761248 on November 19, 2021 and December 9, 2021, respectively, which was found conditionally acceptable on January 28, 2022.^c However, BLA 761248 received a complete response (CR) letter due to clinical deficiencies on January 18, 2023.

Thus, Eli Lilly submitted the name, Kisunla, for review on June 12, 2023 under BLA 761248 with their response to the January 18, 2023 CR letter. We note that all product characteristics remain the same.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission and prescribing information received on June 12, 2023.

- Intended Pronunciation: kih-SUHN-lah
- Nonproprietary Name: donanemab-azbt
- Indication of Use: treatment of Alzheimer’s disease
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 350 mg/20 mL (17.5 mg/mL)
- Dose and Frequency: 700 mg every 4 weeks for the first 3 doses, followed by 1,400 mg every 4 weeks.
- How Supplied: 20 mL single-dose glass vial
- Storage: (Unopened Vial) Store refrigerated at 2°C to 8°C (36°F to 46°F). Keep the vial in the outer carton to protect from light. Do not freeze or shake. If refrigeration is not

^b Morris, C. Proprietary Name Review for (b) (4) (IND 109157). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 SEP 16. PNR ID No. 2021-1044724106.

^c Morris, C. Proprietary Name Review for Kisunla (IND 109157 / BLA 761248). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2022 JAN 28. PNR ID No. 2021-1044724295 / 2021-1044724321.

available, may be stored at room temperature (20°C to 25°C [68°F to 77°F]) for up to 3 days.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

Eli Lilly did not provide a derivation or intended meaning for the proposed proprietary name, Kisunla, in their submission.

This proprietary name is comprised of a single word that contains the letter string "LA", which is a medical abbreviation meaning "long acting" and has been used as a modifier in marketed prescription products. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter string "LA" is a common letter string in existing drug nomenclature (e.g., Ngenla, Khedezla, Vyfemla, and Baxdela) and we are unaware of post-market reports of medication errors associated with this specific abbreviation through our routine surveillance. As the letter string "LA" is located at the end of the name, we evaluated the potential risk of misinterpreting the proposed proprietary name as "[drug name similar to Kisun] LA" and did not identify any new concerns.^e Therefore, in this case we do not object to the proposed proprietary name based on the inclusion of the medication abbreviation and agree with the assessment in our previous review.

Kisunla does not contain any additional components (i.e., route of administration, dosage form, etc.) that can contribute to medication error.

^d USAN stem search conducted on July 12, 2023.

^e POCA search conducted on July 21, 2023 in version 5.2.

2.2.3 Comments from Other Review Disciplines at Initial Review

On June 22, 2023, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Kisunla at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-five practitioners participated in DMEPA's prescription studies for Kisunla.

One CPOE participant erroneously selected the name Brukinsa from a "dynamic contains" pick list. Brukinsa (zanubrutinib) is a Bruton tyrosine kinase (BTK) inhibitor approved for the treatment of adult patients with relapsed or refractory mantle cell lymphoma or marginal zone lymphoma, Waldenstrom macroglobulinemia and chronic lymphocytic leukemia or small lymphocytic lymphoma, and is currently marketed as an 80 mg oral capsules that is administered either as 160 mg (2 capsules) twice daily or 320 mg (4 capsules) once daily. In this case, the participant typed "kins" in the search field; therefore, the correct name, Kisunla, did not populate the pick list. In fact, the only name to populate the pick list was "Brukinsa". We also note the participant took 49 seconds to submit their response, suggesting the participant knew the correct name was not listed, however the simulation software does not allow the participant to go back to the previous page at this time. Therefore, we determined the participant selected the only answer that was available to select. We did not evaluate this result further given the response is an artifact related to the design of the simulation software, which doesn't allow the participant to abandon the study or go back to the previous screen. As such, we conclude the risk for a medication error to occur between this name pair is unlikely (see Appendix F).

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^f identified 35 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. We re-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 name. We note that none of the product characteristics have changed, and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 2 names not previously analyzed. 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 the FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

^f POCA search conducted on July 13, 2023 in version 5.2.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 3 names contained in Table 1 determined none of the names will pose a risk for confusion with Kisunla as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On August 31, 2023, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

3 CONCLUSION

The proposed proprietary name, Kisunla, is conditionally acceptable.

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

3.1 COMMENTS TO ELI LILLY AND COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on June 12, 2023 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.[§]

[§] 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, Cerner RxNorm, 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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 $\geq 70\%$).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

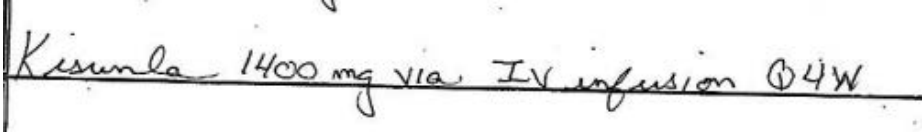
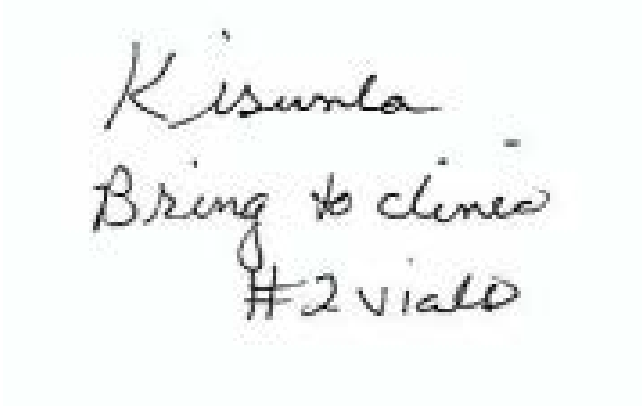
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Kisunla Study (Conducted on July 12, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Kisunla Bring to clinic #2 vials
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Kisunla	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Kisunla - 2023-07-12					
People Received Study: 253					
People Responded: 75					
Total	22	18	18	17	75
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BRUKINSA	0	0	0	1	1
KESSONLA	0	0	1	0	1
KEYSANLA	0	0	1	0	1
KIMSUNLA	1	0	0	0	1
KISEMLA	0	0	2	0	2
KISOMLA	0	0	1	0	1
KISSUMLA	0	0	2	0	2
KISUMLA	0	1	2	0	3
KISUNLA	21	16	7	16	60
KISUNLUH	0	0	1	0	1
KISUNTA	0	1	0	0	1
TISUNLA	0	0	1	0	1

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

No.	Proposed name: Kisunla Established name: donanemab-azbt Dosage form: injection Strength(s): 350 mg/20 mL (17.5 mg/mL) Usual Dose: 700 mg (40 mL) or 1,400 mg (80 mL) every 4 weeks	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.
N/A			

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
N/A		

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Kisunla Established name: donanemab-azbt Dosage form: injection Strength(s): 350 mg/20 mL (17.5 mg/mL) Usual Dose: 700 mg (40 mL) or 1,400 mg (80 mL) every 4 weeks	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
N/A			

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Brukina	52

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
N/A			

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusionⁱ.

No.	Name	POCA Score (%)
1.	Skin-Lube	57
2.	Sovuna***	56

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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/s/

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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:	7/29/2022
Responsible OND Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	BLA 761248
Product Name and Strength:	Kisunla (donanemab-azbt) injection 350 mg/20 mL (17.5 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Eli Lilly and Company (Lilly)
FDA Received Date:	May 18, 2022
Nexus NPNS ID #:	2022-108
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Division Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Lilly for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761248.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On May 18, 2022, Lilly submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Lilly also provided findings from an external study conducted by the (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 Lilly:

Table 1. Suffixes submitted by Lilly***	
1.	azbt
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

^a FDA Suffix Cover Letter . Indianapolis (IN): Eli Lilly and Company; 2022 May 18. Available from:

[\\CDSESUB1\evsprod\bla761248\0002\m1\us\lilly-onan-mr-add1-fda-suffix-cover-letter---final--04-11-20.pdf](#)

^b Biological Proper Name Suffix Report. (b) (4) 2022 Apr 11. Available from:

[\\CDSESUB1\evsprod\bla761248\0002\m1\us\lilly-onan-mr-add1-fda-suffix-report---final--04-11--2022-.pdf](#)

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

2.1 donanemab-azbt

Lilly's first proposed suffix, -azbt, is comprise of 4 distinct letters.

We determined that the proposed suffix -azbt, 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 July 27, 2022, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Neurology 1 (DN 1) on July 29, 2022.

4 CONCLUSION

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

4.1 Recommendations for Eli Lilly and Company

We find the nonproprietary name, donanemab-azbt, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, donanemab-azbt will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

^a See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry:

Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

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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:	January 28, 2022
Application Type and Number:	IND 109157 / BLA 761248
Product Name and Strength:	Kisunla (donanemab) injection, 350 mg/20 mL (17.5 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Eli Lilly and Company (Eli Lilly)
PNR ID #:	2021-1044724295 / 2021-1044724321
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Kisunla, 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. Eli Lilly submitted an internally conducted name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Eli Lilly previously submitted the proposed proprietary name, (b) (4) *** on August 6, 2021. However, we found the name, (b) (4) *** unacceptable “because, as proposed, it creates a misleading impression regarding the efficacy of the drug”.^a

Thus, Eli Lilly submitted the name, Kisunla, for review under IND 109157 and BLA 761248 on November 19, 2021 and December 9, 2021, respectively.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 19, 2021 and December 9, 2021.

- Intended Pronunciation: kih-SUHN-lah
- Nonproprietary Name: donanemab
- Indication of Use: (b) (4) of Alzheimer’s disease
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 350 mg/20 mL (17.5 mg/mL)
- Dose and Frequency: 700 mg every 4 weeks for the first 3 doses, followed by 1,400 mg every 4 weeks (b) (4)
- How Supplied: 20 mL glass vial
- Storage: (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

^a Morris, C. Proprietary Name Review for (b) (4) (IND 109157). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2021 SEP 16. PNR ID No. 2021-1044724106.

The Office of Prescription Drug Promotion (OPDP) determined that Kisunla would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP’s assessment for Kisunla.

2.2 SAFETY ASSESSMENT

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

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

Eli Lilly did not provide a derivation or intended meaning for the proposed proprietary name, Kisunla, in their submission.

This proprietary name is comprised of a single word that contains the letter pair “la”, which is a common medical abbreviation meaning “long acting” and has been used as a modifier in marketed prescription products. We typically discourage the inclusion of medical abbreviations in proprietary names; however, we consider the risk of the proposed proprietary name Kisunla being misinterpreted as “Kisun or Kisun La” is unlikely. Thus, we do not object to the inclusion of the letters ‘la’ in this case.

Beyond the letter pair “la”, Kisunla does not contain any additional components (i.e. route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 7, 2022, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Kisunla at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA’s prescription studies for Kisunla.

One CPOE participant erroneously selected the currently marketed product, Kinrix, from a “dynamic begins” pick list. Kinrix is vaccine containing diphtheria and tetanus toxoids, acellular pertussis, and inactivated polio, and is available as single-dose pre-filled syringes. The participant typed “kin” in the search field; therefore, the correct name, Kisunla, did not populate the pick list. The participant provided the comment “This one looked like Kinsula [sic] but it will not come up in the drop-down options”. Therefore, we determined the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. As such, we conclude the risk for a medication error to occur between this name pair is unlikely (see Appendix F).

^b USAN stem search conducted on January 4, 2022.

Otherwise, the responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^c identified 34 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. 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, the Sponsor's internal name study, 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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	29
Low similarity name pair: combined match percentage score $\leq 54\%$	5

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

Our analysis of the 35 names contained in Table 1 determined none of the names will pose a risk for confusion with Kisunla as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On January 28, 2022, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

^c POCA search conducted on January 4, 2022 in version 4.4.

3 CONCLUSION

The proposed proprietary name, Kisunla, is acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO ELI LILLY AND COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on December 9, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.^d

^d 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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^e. 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.

^e 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed 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 $\geq 70\%$).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

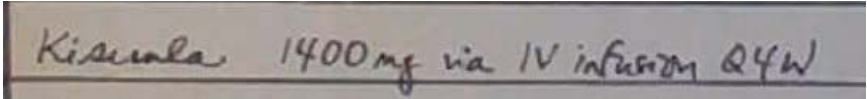
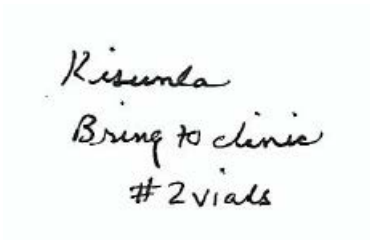
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Kisunla Study (Conducted on December 10, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Kisunla Bring to clinic #2 vials
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Kisunla	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
93 People Responded

Study Name: Kisunla

Total	24	28	20	21	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
CASONA	0	0	1	0	1
CASSUMLA	0	0	1	0	1
CASUNLA	0	0	1	0	1
KASSANLA	0	0	1	0	1
KASUNLA	0	0	1	0	1
KESAMLA	0	0	1	0	1
KESUNLA	0	0	2	0	2
KINRIX	0	1	0	0	1
KINSERAKA	0	0	0	1	1
KINSONLA	0	0	1	0	1
KINSUALA	0	0	0	1	1
KINSULA	1	0	0	0	1
KISCAMLA	0	0	0	1	1
KISCENLA	0	0	0	1	1
KISEINLA	0	0	0	1	1
KISERALA	0	0	0	1	1
KISERNLA	0	0	0	2	2
KISERULA	0	0	0	1	1
KISIUALA	0	0	0	1	1
KISONLA	0	0	1	0	1
KISSANLA	0	0	1	0	1
KISSUNLA	0	0	1	0	1
KISUALA	0	0	0	5	5
KISUMLA	3	0	1	0	4
KISUNLA	20	27	3	4	54
KISURALA	0	0	0	1	1
KYSNLA	0	0	1	0	1
QUISALMRA	0	0	1	0	1
QUISUNLA	0	0	1	0	1
QUSOMLA	0	0	1	0	1
UPZYST	0	0	0	1	1

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

No.	Proposed name: Kisunla Established name: donanemab Dosage form: injection Strength(s): 350 mg/20 mL (17.5 mg/mL) Usual Dose: 700 mg or 1,400 mg every 4 weeks	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.	Kisunla	100	Subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Tafinlar	62
2.	Kinsolus***	60

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Kisunla Established name: donanemab Dosage form: injection Strength(s): 350 mg/20 mL (17.5 mg/mL) Usual Dose: 700 mg or 1,400 mg every 4 weeks	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.	Kisqali	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, the infixes (-sun- vs -sq-) provide some differentiation. Specifically, Kisqali contains the downstroke letter “q” in the fourth position, whereas, Kisunla does not contain any downstroke letters, which provides the names different shapes. Phonetically, the second syllables (SUHN vs kah’) and third syllables (lah vs lee) sound different. Furthermore, the following product characteristics may provide additional differentiation, if included: strength

No.	Proposed name: Kisunla Established name: donanemab Dosage form: injection Strength(s): 350 mg/20 mL (17.5 mg/mL) Usual Dose: 700 mg or 1,400 mg every 4 weeks	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
			(350 mg/20 mL or 17.5 mg/mL vs 200 mg), dosage form (injection vs tablet), route of administration (intravenous infusion vs oral), dose (700 mg or 1,400 mg vs 600 mg), and frequency (weekly, every 2 weeks, or every 4 weeks vs once daily).
2.	Defen-La	61	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
4.	Kanuma	55	This name pair has sufficient orthographic and phonetic differences.
5.	Sunlenca***	55	This name pair has sufficient orthographic and phonetic differences.
6.	Insulin	54	This name pair has sufficient orthographic and phonetic differences.
7.	Uni-Lan	50	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Kinrix	50

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) ***	67	Proposed proprietary name found acceptable by DMEPA (OSE RCM 2017-17474652 dated 03/06/2018) under IND 064119. However, the Applicant withdrew the name and NDA 210557 was approved under the proprietary name Vyleesi.
2.	De-Sone La	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Ketonal	62	International product marketed in Poland, Russia, the Ukraine, and the Czech Republic.
4.	Nasal La	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Sulla	54	Brand discontinued with no generic equivalents available. NDA 016000 withdrawn FR effective 05/29/2002.
6.	Insulase	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Skysona***	64
2.	Tussanil	63
3.	Hysingla	60
4.	Tis-U-Sol	60
5.	(b) (4) ***	60

^f 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 (%)
6.	Desonil	59
7.	Bicillin L-A	56
8.	Bisphenol A	56
9.	Iso-Blu	56
10.	Isolan	56
11.	Quinalan	56
12.	Qutenza	56
13.	Ephensin-La	55
14.	Fasenra	55
15.	(b) (4) ***	55
16.	Nesina	55
17.	Sufenta	55
18.	Visine-A	55

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/s/

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