CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761197Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum

FROM: Lubna Merchant, M.S., PharmD.
Deputy Director, OMEPRM
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

THROUGH: Gerald Dal Pan, M.D., M.H.S.,
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

SUBJECT: Evaluation of the nonproprietary name for BLA 761197.

TO: BLA 761197

Genentech submitted a new Biologics License Application (BLA 761197) pursuant to Section 351(a) of the Public Health Service Act, for a new formulation of a currently approved biological product: Lucentis (ranibizumab) (BLA 125156).

Lucentis (ranibizumab) is a vascular endothelial growth factor A (VEGF-A) inhibitor, and currently approved for intravitreal injection for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), and myopic choroidal neovascularization (mCNV). Lucentis is currently supplied as single-use prefilled syringe (10 mg/mL and 6 mg/mL) and single-use vials (10 mg/mL and 6 mg/mL) designed to provide 0.05 mL for intravitreal injection to be administered once a month. Genentech is the license holder for BLA 125156 and applicant for BLA 761197.

The new formulation in BLA 761197 is only indicated for Neovascular (wet) AMD and is to be administered intravitreally via a port delivery system (PDS). The Port Delivery System with ranibizumab is a drug device combination product that includes a surgically implantable,

permanent[1] ocular delivery device (implant), ancillary devices, and a customized formulation of ranibizumab 10 mg/0.1 mL (100 mg/mL). The PDS implant is a refillable, permanent, intraocular device uniquely designed for continuous delivery of ranibizumab (100 mg/mL). The PDS is designed to maintain therapeutic drug concentrations in the vitreous for longer durations than the available anti-VEGF treatments administered by intravitreal injection. The proposed dosage form of the PDS will be a single-dose vial designed to deliver 0.1 mL of 10 mg/0.1 mL ranibizumab. The proposed dosing regimen consists of an initial fill of the implant and surgical insertion of the filled implant into the patient's eye, followed by refills of the implant (ranibizumab 100 mg/mL formulation) every 24 weeks. This new marketing application for proposed ranibizumab in PDS cross references BLA 125156.

Under FDA's prescription drug user fee bundling policy, different dosage forms should be submitted in separate original applications unless the products are quantitatively and qualitatively identical (drugs) or alike (biological products) in composition.[2] After reviewing the compositions of the proposed and marketed ranibizumab formulations, the Office of Biotechnology Products (OBP) determined that these biological products are quantitatively and qualitatively alike for user fee purposes and could be managed as a sBLA submission. However, Genentech has submitted this formulation as a new BLA.

Genentech is proposing to have a separate U.S. prescribing information (USPI) that would include the proposed product and proposed indication. Genentech is proposing to have a different proprietary name for the proposed formulation, Susvimo.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017 stating the Agency's intention to designate proper names that include four-letter distinguishing suffixes for biological products.[3] This 351(a) application (BLA 761197) is within the scope of this guidance.

The currently approved formulation for Lucentis (BLA 125156) is also within the scope of the guidance; the draft updated guidance, issued in March 2019, addresses nonproprietary names of biological products licensed under section 351(a) that do not include an FDA-designated suffix.[4] The updated guidance, if finalized, will explain that FDA does not expect the nonproprietary names of such products to be revised in order to accomplish the objectives of the naming convention described in the January 2017 final guidance for industry.

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[1] Although described as 'permanent', the implant can be removed using the 'explant tool'.

[2] See the recommendations in section III.A.3 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

[3] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "naming guidance").

[4] Available at https://www.fda.gov/media/121316/download

We carefully considered whether the nonproprietary name of the new proposed formulation in BLA 761197 should include a suffix or whether the proper name considerations for this product warrant departing from the January 2017 final guidance. Among the factors we have considered are the following:

1. Based on Office of Biotechnology Products' evaluation, the drug substance (DS) in the approved formulation and the proposed formulation are essentially unchanged with respect to product quality attributes. The same reference standard is used for the characterization, release and stability testing of the DS and drug product (DP) in the Lucentis and Susvimo formulations.

2. The ranibizumab DS in the approved Lucentis formulation and the proposed Susvimo formulation share the same (b) (4) The DP container closures are identical, i.e., 2 mL Type (b) (4) glass vials with rubber stopper and aluminum seal.

3. There are minor differences noted in color at release and on stability of the DS and DP between the approved Lucentis and proposed Susvimo formulations, which may be attributed to the differences in protein concentration and excipient composition.

4. We note that the dose (0.5 mg (b) (4) vs. 10 mg) differs between the two formulations. But both formulations are administered via intravitreal route and are indicated for nAMD. The proposed presentation will be a single-dose vial containing ranibizumab formulated at 100 mg/mL (10 mg/0.1 mL). The proposed dosing regimen consists of an initial fill of the implant and surgical insertion of the filled implant into the patient's eye, followed by refills of the implant (ranibizumab 100 mg/mL formulation)

every 24 weeks and serve as an alternative means of delivering ranibizumab in patients with nAMD.

5. We noted above that this change could also be managed under a supplement to the current BLA, which would not have resulted in a change to the proper name under the approach to nonproprietary naming described in the final guidance.

   As noted in the final naming guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. As noted above, the drug substance proposed in this submission, ranibizumab, is essentially unchanged with respect to product quality attributes. Also, as noted above, Genentech is the license holder for BLA 125156 and the Applicant for BLA 761197.

Given the above factors, a suffix would not be designated in this particular case. The addition of a suffix to the nonproprietary name of the proposed formulation, while not adding the suffix to the marketed formulation of Lucentis, could create confusion and would not further the goals of the naming convention.

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving a nonproprietary name without a suffix for this product.[5] We based this determination upon consideration of all the factors outlined above for this BLA. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name format for this BLA. The following comments will be communicated to Genentech in an advice letter.

[5] See 21 C.F.R. § 10.115(d)(3) ("Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.").

Comments for Genentech Pharmaceuticals

We acknowledge that the agency previously notified you that your proposed BLA is within the scope of the Nonproprietary Naming of Biological Products guidance[6] and that FDA intends to assign a four-letter suffix for inclusion in the proper name designated in the license at such time as FDA approves the BLA.

However, we have determined that a suffix will not be designated for this proposed product. Therefore, ranibizumab will be the proper name designated in the license should your 351(a) BLA be approved during this review cycle. You should revise your proposed labels and labeling accordingly and submit the revised proposed labels and labeling to your BLA for our review.

[6] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf

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/s/

LUBNA A MERCHANT
08/23/2021 03:16:12 PM

GERALD J DALPAN
08/23/2021 03:22:55 PM

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:	March 17, 2021
Application Type and Number:	BLA 761197
Product Name and Strength:	Susvimo (ranibizumab) Injection, 10 mg/0.1 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc (Genentech)
Panorama/PNR ID #:	2020-1044397986
DMEPA Safety Evaluator:	Zahra Farshneshani, PharmD
DMEPA Team Leader (Acting):	Valerie S. Vaughan, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Susvimo, 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. Genentech submitted an external name study, conducted by (b) (4), for this proposed proprietary name that was previously reviewed by DMEPA.

1.1 REGULATORY HISTORY

Genentech previously submitted the proposed proprietary name, Susvimo on June 24, 2019. We found the proposed proprietary name, Susvimo, conditionally acceptable on December 2, 2019 under IND 113552.[a]

Thus, Genentech resubmitted the name, Susvimo, for review on December 18, 2020 under BLA 761197.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 18, 2020.

- Intended Pronunciation: suss-VIH-moh
- Active Ingredient: ranibizumab
- Indication of Use: Treatment of neovascular age related macular degeneration (nAMD) (b) (4)
- Route of Administration: intravitreal (through diffusion of ranibizumab from the intraocular implant into the vitreous of the eye)
- Dosage Form: Injection
- Strength[b]: 10 mg/0.1 mL
- Dose and Frequency: Insert one intraocular implant into the vitreous of the eye once. The usual dosage for Susvimo consists of filling the implant with 20 microliters (µL) of ranibizumab (2 mg) prior to surgical implant into the eye, with a fixed refill schedule of every 24 weeks.
- How Supplied: As part of the delivery system, ranibizumab is supplied as a (b) (4). All of the Susvimo drug and device constituents are provided as sterile and are labeled for single-use only. The implant is packaged with the insertion tool assembly in a single sterile barrier system.

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[a] Roosta, N. Proprietary Name Review for Susvimo (IND 113552). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. Panorama No. 2019-32660324.

[b] (b) (4)

- Storage: [redacted] (b) (4) ranibizumab must be refrigerated at 2°C to 8°C (36°F to 46°F) The implant, insertion tool assembly, [redacted] (b) (4) refill needle, and explant tool should be maintained at a room temperature below 25°C (77°F).

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

1.3 MISBRANDING ASSESSMENT

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

1.4 SAFETY ASSESSMENT

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

1.4.1 United States Adopted Names (USAN) Search

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

1.4.2 Components of the Proposed Proprietary Name

Genentech indicated in their submission that the proposed proprietary name, Susvimo, is a coined proprietary name. 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 are misleading or can contribute to medication error.

1.4.3 Comments from Other Review Disciplines at Initial Review

On January 13, 2021, the Division of Ophthalmology (DO) did not forward any comments or concerns relating to Susvimo at the initial phase of the review.

1.4.4 FDA Name Simulation Studies

Eighty-one practitioners participated in DMEPA's prescription studies for Susvimo. 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.

1.4.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 39 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in

[c] USAN stem search conducted on February 25, 2021.

[d] POCA search conducted on February 25, 2021 in version 4.4.

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 five names not previously analyzed. These names are included in Table 1 below.

1.4.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	5
Low similarity name pair: combined match percentage score ≤54%	0

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

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

1.4.8 Discussion of Dual Proprietary Name

The proposed Susvimo (ranibizumab) injection will be an extension of the ranibizumab product line manufactured by Genentech, Inc and marketed under the proprietary name, Lucentis (BLA 125156) which was approved on June 30, 2006. Table 2 summarizes the product characteristics between the two products.

Table 2. Summary of Product Characteristics of Susvimo and Lucentis[e]

	Susvimo (BLA 761197)	Lucentis (BLA 125156)
Active ingredient	ranibizumab	

[e] LUCENTIS [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2017 APR. Available from: https://www.accessdata fda.gov/drugsatfda_docs/label/2017/125156s114lbl.pdf

Indication	Treatment of neovascular age related macular degeneration (nAMD) (b) (4)	Neovascular (Wet) Age-Related Macular Degeneration (AMD) Macular Edema Following Retinal Vein Occlusion (RVO) Diabetic Macular Edema (DME) Diabetic Retinopathy (DR) Myopic Choroidal Neovascularization (mCNV)
Strength	10 mg/0.1 mL	0.3 mg and 0.5 mg
Dose	Insert one intraocular implant into the vitreous of the eye once. The usual dosage for Susvimo consists of filling the implant with 20 microliters (µL) of ranibizumab (2 mg) prior to surgical implant into the eye.	**AMD/RVO/mCNV** 0.5 mg (0.05 mL of 10 mg/mL solution) once monthly **DME/DR** 0.3 mg (0.05 mL of 6 mg/mL solution) once a month
Dosage Form	Injection	Injection
Frequency of administration	Every 24 weeks.	Every 28 days
How Supplied	As part of the delivery system, ranibizumab is supplied as (b) (4) . All of the Susvimo drug and device constituents are provided as sterile and are labeled for single-use only. The implant is packaged with the insertion tool assembly in a single sterile barrier system	**Single-Use Prefilled Syringe** • Each LUCENTIS 0.5 mg carton (NDC 50242-080-03) contains a single-use, prefilled syringe designed to deliver 0.05 mL of 10 mg/mL ranibizumab solution. The prefilled syringe has a non-retractable plunger stopper and a syringe cap consisting of a tamper-evident rigid seal with a rubber tip cap including a Luer lock adapter. The prefilled syringe has a plunger rod and a CLEAR finger grip. The prefilled syringe is sterile and is packed in a sealed tray. • Each LUCENTIS 0.3 mg carton (NDC 50242-082-03) contains a single-use, prefilled syringe designed to deliver 0.05 mL of 6 mg/mL ranibizumab solution. The prefilled syringe has a non-

		retractable plunger stopper and a syringe cap consisting of a tamper-evident rigid seal with a rubber tip cap including a Luer lock adapter. The prefilled syringe has a plunger rod and an ORANGE finger grip. Each prefilled syringe is sterile and is packed in a sealed tray. **Single-use glass vial** • Each LUCENTIS 0.5 mg carton (NDC 50242-080-02) contains a single-use, 2-mL glass vial with a BLUE CAP designed to deliver 0.05 mL of 10 mg/mL ranibizumab solution. • Each LUCENTIS 0.3 mg carton (NDC 50242-082-02) contains a single-use, 2-mL glass vial with a WHITE CAP designed to deliver 0.05 mL of 6 mg/mL ranibizumab solution.
Storage	(b) (4) The implant, insertion tool assembly, (b) (4) refill needle, and explant tool should be maintained at a room temperature below 25°C (77°F).	LUCENTIS should be refrigerated at 2°-8°C (36°-46°F). DO NOT FREEZE. Do not use beyond the date stamped on the label. Protect LUCENTIS prefilled syringes and vials from light and store in the original carton until time of use. Do not open LUCENTIS prefilled syringe sealed tray until time of use.

Although both products contain the same active ingredients, they have different dosages, frequency, strengths, and require different administration techniques. We note that the Applicant did not provide a discussion of the proposal to use a dual proprietary name for this product nor did the external name study include such a discussion.

We have evaluated the risks associated with this naming strategy and note that there is a potential for concomitant therapy since postmarketing experience with other drug products has shown concomitant therapy to be a common type of error when an active ingredient is marketed under

two or more names.[f] However, given these products will have different dosages, frequency, strengths, and administration techniques, managing them under separate names may decrease the likelihood of confusion. Therefore, we do not object to the use of a dual proprietary name in this case. Any residual risk may be managed through labels and labeling mitigations.

1.4.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Ophthalmology (DO). At that time we also requested additional information or concerns that could inform our review. On March 17, 2021, the Division of Ophthalmology (DO) stated no additional concerns with the proposed proprietary name, Susvimo.

2 CONCLUSION

The proposed proprietary name, Susvimo, is acceptable.

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

2.1 COMMENTS TO GENENTECH, INC

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

If any of the proposed product characteristics as stated in your submission, received on December 18, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

[f] The Institute for Safe Medication Practices. "Revatio=Sildenafil=Viagra". January 2009

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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. 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 ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

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

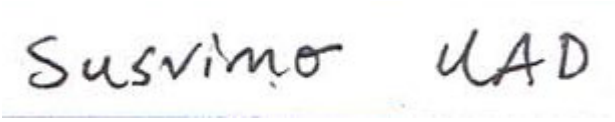
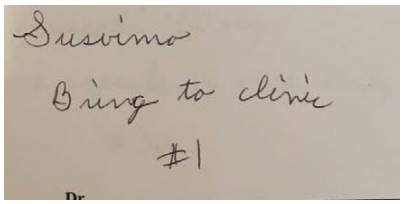
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Susvimo Study (Conducted on February 2, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Susvimo Bring to clinic. Dispense one.
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Susvimo	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Susvimo

As of Date 3/4/2021

210 People Received Study
81 People Responded

Study Name: Susvimo

Total	31	15	13	22	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
CEFVIMO	0	0	1	0	1
CEFZIMO	0	0	2	0	2
SEPZIMO	0	0	1	0	1
SESVYMO	0	0	1	0	1
SEZIMO	0	0	1	0	1
SUBZEMO	0	0	1	0	1
SUBZIMO	0	0	1	0	1
SUSBIMO	1	0	0	0	1

SUSIMO	1	0	0	0	1
SUSTIMO	0	0	1	0	1
SUSVIMA	1	0	0	0	1
SUSVIMO	28	15	1	20	64
SUSVINO	0	0	0	2	2
SUSZIMO	0	0	3	0	3

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

No.	**Proposed name:** Susvimo **Established name:** ranibizumab **Dosage form:** Injection **Strength(s):** 10 mg/0.1 mL **Usual Dose:** Inject one intraocular implant into the vitreous of the eye once	**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.	N/A	N/A	N/A

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.	N/A	N/A

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

No.	**Proposed name:** Susvimo **Established name:** ranibizumab **Dosage form:** Injection **Strength(s):** 10 mg/0.1 mL **Usual Dose:** Inject one intraocular implant into the vitreous of the eye once	**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.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences
2.	(b) (4) ***	59	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.	N/A	N/A

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) ***	60	(b) (4)
2.	Solvadi	58	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[i].

No.	Name	POCA Score (%)
1.	(b) (4) ***	55

[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

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/

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