CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761404Orig2s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	8/8/2024
Responsible OND Division:	Division of General Endocrinology (DGE)
Application Type and Number:	BLA 761404
Product Name and Strength:	Stoboclo (denosumab-bmwo) injection, 60 mg/mL Osenvelt (denosumab-bmwo) injection 120 mg/1.7 mL (70 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
FDA Received Date:	November 30, 2023
Nexus NPNS ID #:	2023-214
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Celltrion for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761404.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 30, 2023, Celltrion submitted a list of five suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Celltrion also provided their evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Celltrion:

Table 1. Suffixes submitted by Celltrion***

1.	bmwo
2.	(b) (4)
3.	
4.	
5.	

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

2.1 denosumab-bmwo

Celltrion's first proposed suffix, -bmwo, is comprised of 4 distinct letters.

We determined that the proposed suffix -bmwo, 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

[a] Nonproprietary Name Review Request and Supporting Analysis BLA 761404. Incheon (Republic of Korea): Celltrion, Inc.; 2023 Nov 30. Available from: \\CDSESUB1\EVSPROD\bla761404\0001\m1\us\nonproprietary-name.pdf

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

devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On August 7, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of General Endocrinology (DGE) on August 8, 2024.

4 CONCLUSION

We find Celltrion's proposed suffix -bmwo acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to denosumab-bmwo. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Celltrion, Inc.

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

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
08/08/2024 02:48:48 PM

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PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	February 26, 2024
Application Type and Number:	BLA 761404
Product Name and Strength:	Osenvelt (denosumab-xxxx) [a] injection, 120 mg/1.7 mL (70 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
PNR ID #:	2023-1044725495
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, denosumab-xxxx, is used throughout this review.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Osenvelt, which was found conditionally acceptable under IND 147751 on October 13, 2023.[b]

Thus, Celltrion submitted the name, Osenvelt, under BLA 761404 for re-review on November 30, 2023. We note that there is a change in the storage requirements (see Section 2.2) to align with the proposed Prescribing Information submitted for IND 147751. All other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Osenvelt, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in storage requirements[c]. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Osenvelt.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 16, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Osenvelt.

2.3 Discussion of Dual Proprietary Name

Celltrion Inc. intends to market denosumab under two different proprietary names: Osenvelt (BLA 761404) and Stoboclo ***(BLA 761404). Table 2 compares the two proposed proprietary names and their respective product characteristics.

Table 2. Relevant Product Information for Osenvelt and Stoboclo***

Product Name	**Osenvelt**	**Stoboclo*** **
Initial Approval Date	N/A	N/A
Intended Pronunciation	oh sen' velt	Stoe bok' loe
Nonproprietary Name	denosumab-xxxx	

[b] Rahbani P. Proprietary Name Review for Osenvelt (IND 147751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Oct 13. PNR ID No. 2023-1044725106.

[c] Under IND 147751, the proprietary name submission stated that the product should be used within (b) (4) days and if not used within (b) (4) days, it should be discarded. Under BLA 761404, the Prescribing Information states that the product should be used within 30 days and if not used within the 30 days, it should be discarded.

Table 2. Relevant Product Information for Osenvelt and Stoboclo***		
Product Name	**Osenvelt**	**Stoboclo*** **
Indication	Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.	Treatment of postmenopausal women with osteoporosis at high risk for fracture Treatment to increase bone mass in men with osteoporosis at high risk for fracture Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
Route of Administration	subcutaneous	
Dosage Form	injection	
Strength	120 mg/1.7 mL (70 mg/mL)	60 mg/mL
Dose and Frequency	Multiple Myeloma and Bone Metastasis from Solid Tumors: 120 mg administered as a subcutaneous injection every 4 weeks. Giant Cell Tumor of Bone: 120 mg administered every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.	60 mg subcutaneous injection once every 6 months.
How Supplied	120 mg/1.7 mL single-dose vial, 1 vial per carton.	Single-dose prefilled syringe, 1 syringe per carton

Table 2. Relevant Product Information for Osenvelt and Stoboclo***		
Product Name	**Osenvelt**	**Stoboclo*** **
Reference Product	Proposed interchangeable biosimilar to US-licensed Reference Product Xgeva (denosumab) BLA 125320.	Proposed interchangeable biosimilar to US-licensed Reference Product, Prolia (denosumab) BLA 125320

Although both products contain the same active ingredients, they have different indications of use, strengths, doses/frequency of administration, and are supplied in different presentations (see Table 2). We note that the Applicant did not provide a discussion of the proposal to use a dual proprietary name for this product. However, we note that US-licensed Reference Products also use a dual proprietary naming strategy (Prolia (denosumab) injection and Xgeva (denosumab) injection).

We 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[d] . However, given these products will have different indications, strengths, doses/frequency of administration, 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.

2.4 COMMUNICATION OF DMEPA'S DETERMINATION

On February 26, 2024, we communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

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

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO CELLTRION, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 30, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

PEGGY M RAHBANI
02/27/2024 11:28:34 AM

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MISHALE P MISTRY
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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	February 26, 2024
Application Type and Number:	BLA 761404
Product Name and Strength:	Stoboclo (denosumab-xxxx)[a] injection, 60 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion Inc (Celltrion)
PNR ID #:	2023-1044725498
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, denosumab-xxxx, is used throughout this review.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Celltrion previously submitted the proposed proprietary name, [redacted] (b) (4) under IND 147751 on April 18, 2023. However, on October 13, 2023, we found the name, [redacted] (b) (4) unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, [redacted] (b) (4).[b]

Thus, Celltrion submitted the name, Stoboclo, for review on November 30, 2023, under BLA 761404.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 30, 2023.

- Intended Pronunciation: Stoe bok' loe
- Active Ingredient: denosumab-xxxx
- Indication of Use:
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture
  - Treatment to increase bone mass in men with osteoporosis at high risk for fracture
  - Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
  - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
  - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 60 mg/mL
- Dose and Frequency: 60 mg subcutaneous injection once every 6 months
- How Supplied: 60 mg/mL single-dose prefilled syringe, 1 syringe per carton.
- Storage: Refrigerate at 2°C to 8°C (36°F to 46°F). Do not freeze. Reach room temperature (up to 25°C/77°F) in the original container prior to administration. Once removed from

[b] Rahbani P. Proprietary Name Review for [redacted] (b) (4) (IND 147751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Oct 13. PNR ID#: 2023-1044725105.

the refrigerator, denosumab-xxxx must not be exposed to temperatures above 25°C/77°F and must be used within 30 days. If not used within 30 days, it should be discarded. Protect from direct light and heat. Avoid vigorous shaking.

- Stoboclo (denosumab-xxxx) is a proposed interchangeable biosimilar to US-licensed Reference Product, Prolia (denosumab) BLA 125320

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 9, 2024, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Stoboclo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-three (n= 93) practitioners participated in DMEPA's prescription studies for Stoboclo. 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.

[c] USAN stem search conducted on December 7, 2023.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

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

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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%	52
Low similarity name pair: combined match percentage score ≤54%	3

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

Our analysis of the 55 names contained in Table 1 determined none of the names will pose a risk for confusion with Stoboclo as described in Appendices C through H.

2.2.8 Discussion of Dual Proprietary Name

Celltrion Inc. intends to market denosumab under two different proprietary names: Stoboclo (BLA 761404) and Osenvelt*** (BLA 761404). Table 2 compares the two proposed proprietary names and their respective product characteristics.

Table 2. Relevant Product Information for Stoboclo and Osenvelt*

Product Name	Stoboclo	Osenvelt***
Initial Approval Date	N/A	N/A
Intended Pronunciation	stoe bok’ loe	oh sen' velt
Nonproprietary Name	denosumab-xxxx	
Indication	Treatment of postmenopausal women with osteoporosis at high risk for fracture.	Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

[d] POCA search conducted on December 7, 2023 in version 5.2.

Table 2. Relevant Product Information for Stoboclo and Osenvelt***		
Product Name	**Stoboclo**	**Osenvelt*** **
	Treatment to increase bone mass in men with osteoporosis at high risk for fracture Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Route of Administration	subcutaneous	
Dosage Form	injection	
Strength	60 mg/mL	120 mg/1.7 mL (70 mg/mL)
Dose and Frequency	60 mg subcutaneous injection once every 6 months	Multiple Myeloma and Bone Metastasis from Solid Tumors: 120 mg administered as a subcutaneous injection every 4 weeks. Giant Cell Tumor of Bone: 120 mg administered every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.
How Supplied	Single-dose prefilled syringe, 1 syringe per carton	120 mg/1.7 mL single-dose vial, 1 vial per carton
Reference Product	Proposed interchangeable biosimilar to US-licensed Reference Product, Prolia (denosumab) BLA 125320	Proposed interchangeable biosimilar to US-licensed Reference Product, Xgeva (denosumab) BLA 125320

Although both products contain the same active ingredients, they have different indications of use, strengths, doses/frequency of administration, and are supplied in different presentations (see

Table 2). We note that the Applicant did not provide a discussion of the proposal to use a dual proprietary name for this product. However, we note that US-licensed Reference Products (Prolia (denosumab) injection and Xgeva (denosumab) injection) also use a dual proprietary naming strategy.

We 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[e] . However, given these products will have different indications, strengths, dose and frequency of administration, 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.

2.2.9 Communication of DMEPA's Determination

On February 26, 2024, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Stoboclo, is conditionally acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO CELLTRION INC

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

[e] 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. [f]

***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.

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

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

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

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

proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?

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

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

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

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

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

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

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Stoboclo Study (Conducted on December 15, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: Stoboclo 60mg SQ once Outpatient Prescription: Patient _____ Date _____ Address _____ ℞ Stoboclo 60mg SQ once q 6 months #1 prefilled syringe MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. _____ DEA No._____ Address _____ Telephone _____	Stoboclo 60 mg subcutaneous once every 6 months dispense # 1 prefilled syringe
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Stoboclo	

FDA Prescription Simulation Responses (Aggregate Report)

Aggregate Report

As of Date: 01/03/2024 12:11

Study Name: Stoboclo - 2023-12-15

People Received Study: 167

People Responded: 93

Total	25	23	22	23	93
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
STILBACLO	0	0	1	0	1
STILVAKLO	0	0	1	0	1
STOBACHLO	0	0	1	0	1
STOBACKLO	0	0	1	0	1
STOBACLO	0	0	8	0	8
STOBACLOW	0	0	1	0	1
STOBAKLO	0	0	2	0	2
STOBAQALO	0	0	1	0	1
STOBOCLO	15	18	2	23	58
STOBODO	4	0	0	0	4
STOBORLO	0	1	0	0	1
STOBOZLO	0	3	0	0	3
STOSOCLO	5	0	0	0	5
STOSODO	1	0	0	0	1
STOVACLO	0	0	3	0	3
STOWBLOCKO	0	0	1	0	1
STROBOCLO	0	1	0	0	1

** U.S. FDA - RX Study*

** RX Study Version 4.6.3 (2023-12-04)*

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

No.	**Proposed name:** Stoboclo **Established name:** denosumab-xxxx **Dosage form:** injection **Strength(s):** 60 mg/mL **Usual Dose:** 60 mg subcutaneous injection once every 6 months	**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.	Stoboclo	100	Name subject of this review.

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

No.	Name	POCA Score (%)
1.	Steglatro	56
2.	Tambocor	56

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

No.	**Proposed name:** Stoboclo **Established name:** denosumab-xxxx **Dosage form:** injection **Strength(s):** 60 mg/mL **Usual Dose:** 60 mg subcutaneous injection once every 6 months	**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.	Sytobex	63	This name pair has sufficient orthographic and phonetic differences.
2.	Stadol	62	Orthographically, the infixes/suffixes (‘boclo’ versus ‘dol’) of this name pair have sufficient differences. Additionally, the lengths of the names are dissimilar when scripted (eight versus six letters). Phonetically, Stoboclo contains an extra syllable and the second/third syllables of this name pair (bok’ loe versus dol) sound different.
3.	Stiolto	61	Orthographically, the upstroke letter ‘l’ in the 5th position in Stiolto not present in Stoboclo and the upstroke letter ‘b’

No.	**Proposed name:** Stoboclo **Established name:** denosumab-xxxx **Dosage form:** injection **Strength(s):** 60 mg/mL **Usual Dose:** 60 mg subcutaneous injection once every 6 months	**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**
			in the 4th position in Stoboclo not present in Stiolto provide some orthographic differences. Phonetically, the ending sound of the 1st syllables (‘Stoe’ vs. ‘Ste’), and the second syllables (‘bok’’ vs ‘ol’) sound different. The following differences in product characteristics may also help to minimize the risk of errors: Both products do not overlap in dosage form (inhalation spray vs. injection) or route of administration (oral inhalation vs. subcutaneous), if included on a prescription/medication order. Furthermore, the dose/frequency of administration (60 mg every 6 months vs. two actuations once daily) does not overlap. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
4.	(b) (4) ***	60	(b) (4)

No.	**Proposed name:** Stoboclo **Established name:** denosumab-xxxx **Dosage form:** injection **Strength(s):** 60 mg/mL **Usual Dose:** 60 mg subcutaneous injection once every 6 months	**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**
			(b) (4) When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
5.	Sorbitol	60	This name pair has sufficient orthographic and phonetic differences.
6.	Stromectol	60	This name pair has sufficient orthographic and phonetic differences.
7.	Stabec	58	This name pair has sufficient orthographic and phonetic differences.
8.	Tobrasol	58	This name pair has sufficient orthographic and phonetic differences.
9.	Statrol	58	This name pair has sufficient orthographic and phonetic differences.
10.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
11.	Stomax	58	Orthographically, the lengths of the names differ by two letters and the infixes/suffixes differ (max versus boclo). Phonetically, Stoboclo has an extra syllable and the second/third syllables (‘bok loe’ vs ‘max’) of this name pair sound different. The following differences in product characteristics may also help to minimize the risk of errors:

No.	**Proposed name:** Stoboclo **Established name:** denosumab-xxxx **Dosage form:** injection **Strength(s):** 60 mg/mL **Usual Dose:** 60 mg subcutaneous injection once every 6 months	**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**
			Both products do not overlap in route of administration (subcutaneous vs. oral) or dosage form (injection vs. capsule), if included on a prescription/order. Furthermore, the frequency of administration (once every 6 months vs. up to four times daily or as directed) does not overlap. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
12.	Statobex	57	This name pair has sufficient orthographic and phonetic differences.
13.	Blis-To-Sol	56	This name pair has sufficient orthographic and phonetic differences.
14.	Soltamox	55	This name pair has sufficient orthographic and phonetic differences.
15.	Sotalol	55	This name pair has sufficient orthographic and phonetic differences.
16.	Istodax	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Fe-Stool	54
2.	Isoclor	54
3.	Sochlor	54

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.	S-T Febrol	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Stool-Lax	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Clostebol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Stanozolol	60	NDA 012885 withdrawn FR effective 08/20/2010. Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Stilnoct	60	International product marketed in Finland, Ireland, Netherlands, Norway, Sweden, Belgium, and Denmark. Formerly marketed in Czech Republic and United Kingdom.
6.	Sevoflo	58	Veterinary Product.
7.	Sno Pilo	58	International product formerly marketed in Ireland and the United Kingdom.
8.	Soni-Slo	58	International product formerly marketed in Ireland and the United Kingdom.
9.	Stoxil	58	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 013934 and NDA 015868 withdrawn FR effective 09/17/2001.
10.	Stafoxil	57	International product formerly marketed in Netherland, Ireland and the United Kingdom.
11.	Stamoist La	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Steviol	57	Name identified in RxNorm database. It is a powder for compounding.
13.	Stesolid	56	International product formerly marketed in Germany, Switzerland, Check Republic, Hungary, United Kingdom, Israel, and Thailand. Market in Ireland, Indonesia, Norway, Netherlands, Portugal, Spain Germany, Hong Kong, Austria, Denmark, Finland, New Zealand, Singapore, and Sweden.
14.	Stilbestrol	56	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 004056 withdrawn FR effective 9/13/2000.
15.	Stimlor	56	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
16.	Ceberclon	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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

No.	Name	POCA Score (%)
1.	C-Topical	62
2.	Probucol	58
3.	Pseudochlor	58
4.	Pseudocot	58
5.	Pseudocot-T	58
6.	Topicool	58
7.	Cotabflu	57
8.	Bisabolol	56
9.	Coldloc-La	56
10.	Folbecal	56
11.	Nascobal	56
12.	Ostilox	56
13.	Q-Sorb Co Q-10	56
14.	Tetmosol	56
15.	Cobutolin	55
16.	Ketochlor	55
17.	Totamol	55

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

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