CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761436Orig1s000
761436Orig2s000

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:	June 20, 2025
Responsible OND Division:	Division of General Endocrinology (DGE)
Application Type and Number:	BLA 761436
Product Name and Strength:	Boyasa (denosumab-kyqq) injection, 60 mg/mL Aukelso (denosumab-kyqq) injection, 120 mg/1.7 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
Nexus NPNS ID #:	2024-266
DMEPA 2 Biologics Suffix Specialist:	Carlos Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 Purpose of Review

This review summarizes our evaluation of the four-letter suffix –kyqq for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761436.

2 Regulatory History

Biocon was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter.[a]

3 Assessment of the Nonproprietary Name

denosumab-kyqq

FDA-designated a four-letter suffix, -kyqq. This suffix was evaluated using the principles described in the Nonproprietary Naming of Biological Products guidance.[b]

We determined that the FDA-designated suffix -kyqq, is not too similar to any other product's suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could lead be misinterpreted, and does not make misrepresentations with respect to safety and efficacy of the product.

4 Communication of DMEPA 1 Analysis

These findings were shared with OPDP. On June 18, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of General Endocrinology (DGE) on June 18, 2025.

[a] Mistry, M. Nonproprietary Name General Advice Letter for BLA 761436. Silver Spring (MD): FDA, CDER, OSE, OMEPRM, DMEPA 1 (US) 2024 Oct 11.

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

5 Conclusion

We find the suffix –kyqq acceptable and recommend the nonproprietary name denosumab-kyqq be used throughout the draft labels and labeling. DMEPA 1 will communicate our findings to the Applicant via letter.

5.1 Recommendations for Biocon Biologics Inc.

We find the nonproprietary name, denosumab-kyqq, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, denosumab-kyqq 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. 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
06/20/2025 11:48:32 AM

MISHALE P MISTRY
06/20/2025 12:08:32 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	March 26, 2025
Application Type and Number:	BLA 761436
Product Name, Dosage Form, and Strength:	Aukelso (denosumab-xxxx)[a] injection, 120 mg/1.7 mL (70 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2025-1044726231
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder denosumab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Aukelso, 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. Biocon submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Biocon previously submitted the proposed proprietary name, [redacted] (b) (4) *** under BLA 761436 on September 16, 2024. However, on December 3, 2024, we found the name, [redacted] (b) (4) ** unacceptable due to orthographic similarities and overlapping product characteristics with the proprietary name, [redacted] (b) (4)

Thus, Biocon submitted the proposed proprietary name, Aukelso, for review on January 10, 2025 under BLA 761436.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 10, 2025[d] and the prescribing information received on September 16, 2024.[e]

Table 1. Relevant Product Information for Aukelso	
Intended pronunciation:	aw kel' soe
Nonproprietary name:	denosumab-xxxx
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.
Dosage Form:	injection

[b] Proprietary Name Safety Summary for Aukelso. [redacted] (b) (4) 2025 Jan 3. Available from: \\CDSESUB1\evsprod\BLA761436\0012\m1\us\118-proprietary-names\annexure-proprietary-name-assessment-report-aukelso.pdf.

[redacted] (b) (4)

[d] Request for Proprietary Name Review (Aukelso, BLA 761436). Cambridge (MA): Biocon Biologics Inc.; 2025 Jan 10. Available from: \\CDSESUB1\evsprod\BLA761436\0012\m1\us\118-proprietary-names\request-for-proprietary-name-review-aukelso.pdf

[e] Proposed prescribing information for Aukelso. Cambridge (MA): Biocon Biologics Inc.; 2024 Sep 16. Available from: \\CDSESUB1\evsprod\BLA761436\0001\m1\us\114-labeling\draft\labeling\draft-labeling-text-vial-clean.doc

Table 1. Relevant Product Information for Aukelso	
Strength:	120 mg/1.7 mL (70 mg/mL)
Route of administration:	Subcutaneous
Dose and frequency:	Multiple myeloma and bone metastasis from solid tumors: • 120 mg every 4 weeks Giant cell tumor of bone: • 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the the first month of therapy Hypercalcemia of malignancy: • 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy
How Supplied:	Single-dose vial
Storage:	Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Once removed from the refrigerator, product must not be exposed to temperatures above 25°C/77°F (b) (4) and must be used within 30 days. Discard if not used within the 30 days. Do not use after the expiry date printed on the label.
Reference Product:	Aukelso (denosumab-xxxx) is a proposed interchangeable to US-licensed Reference Product, Xgeva (denosumab) BLA 125320

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Aukelso 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 Aukelso. The Division of General Endocrinology (DGE) did not comment on the findings of OPDP's assessment for Aukelso.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[f] USAN stem search conducted on February 21, 2025.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Biocon did not provide a derivation or intended meaning for the proposed proprietary name, Aukelso, in their submission. This proposed proprietary name is comprised of a single word that contains the letter strings "AU" and "LS", which are medical abbreviations for "each ear" and "liquid suspension", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we evaluated the potential risk of misinterpreting the proposed proprietary name Aukelso as "AU [drug name similar to Kelso]". A POCA search of the name "Kelso" did not identify any names that would pose a risk for confusion.[g] Additionally, we determined that the location of the abbreviation "LS" in the middle of the proposed proprietary name, Aukelso, makes it unlikely for the "LS" letter string to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the "AU" and "LS" letter strings in this case.

Beyond these noted abbreviations, we note that Aukelso does not contain any additional components (i.e., modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Aukelso at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

One hundred and one (101) practitioners participated in DMEPA's prescription studies for Aukelso.

One respondent in the Outpatient study misinterpreted the proposed proprietary name as "Aubelso", which is a close variation of the proposed proprietary name, (b) (4)***. We evaluated the name pair, Aukelso and (b) (4)***, further and find that there are sufficient orthographic, phonetic, and product characteristic differences. Orthographically, the names begin with different letters (A *versus* U), and infixes (-ukels- versus -besl-) look different when scripted, providing some orthographic differences. Phonetically, the first syllables ("aw" *versus* "yoo"), second syllables ("kel" *versus* "beh") sound different when spoken. These differences are further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[h], which calculates a combined orthographic and phonetic score of 52%, indicating low similarity. Additionally, the products differ in route (subcutaneous *versus* oral), dosage form (injection *versus* tablets), and frequency of administration (every 4 weeks *versus* once daily). These product characteristics may provide further differentiation if included on a medication order. Thus, we find the name pair has sufficient orthographic, phonetic, and product characteristic differences, and (b) (4)*** is included in Appendix E.

[g] POCA search conducted on February 21, 2025 in version 5.9.

[h] POCA search conducted on February 21, 2025 in version 5.9.

Two respondents in the Inpatient study misinterpreted the proposed proprietary name as "Aukebo", which is a close variation of the marketed name, Okebo (doxycycline monohydrate). We evaluated the name pair, Aukelso and Okebo, further and find that there are sufficient orthographic, phonetic, and product characteristic differences. This is supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[i], which calculates a combined score of 47%, orthographic score of 54%, and phonetic score of 40%, indicating low similarity. Additionally, the products differ in route (subcutaneous *versus* oral), dosage form (injection *versus* capsules), strength (120 mg/1.7 mL (70 mg/mL) *versus* 50 mg, 75 mg, and 100 mg), and frequency of administration (every 4 weeks *versus* once or twice daily for 7-10 days). These product characteristics may provide further differentiation if included on a medication order. Thus, we find the name pair has sufficient orthographic, phonetic, and product characteristic differences, and Okebo is included in Appendix E.

One respondent in the Verbal study misinterpreted the proposed proprietary name as "Ocelso", which is a close variation of the marketed name, Ocella (drospirenone/ethinyl estradiol). We evaluated the name pair, Aukelso and Ocella, further and find that there are sufficient orthographic, phonetic, and product characteristic differences. This is supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[j], which calculates a combined score of 44%, orthographic score of 50%, and phonetic score of 38%, indicating low similarity. Additionally, the products differ in route (subcutaneous *versus* oral), dosage form (injection *versus* tablets), and frequency of administration (every 4 weeks *versus* once daily). These product characteristics may provide further differentiation if included on a medication order. Thus, we find the name pair has sufficient orthographic, phonetic, and product characteristic differences, and Ocella is included in Appendix E.

The remaining responses did not overlap with any currently marketed products, nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[k] identified 20 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

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[i] POCA search conducted on February 21, 2025 in version 5.9.

[j] POCA search conducted on February 21, 2025 in version 5.9.

[k] POCA search conducted on February 21, 2025 in version 5.9.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	19
Low similarity name pair: combined match percentage score ≤54%	2

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 23 names contained in Table 2 determined none of the names will pose a risk for confusion with Aukelso as described in Appendices C through H.

2.2.8 DISCUSSION OF DUAL PROPRIETARY NAME

Biocon intends to market denosumab-xxxx under two different proprietary names: Bosaya*** (BLA 761436) and Aukelso (BLA 761436). Table 3 compares the two proposed proprietary names and their respective product characteristics.

Table 3. Relevant Product Information for Bosaya*** and Aukelso		
Product Name	Bosaya*** (BLA 761436)[l]	Aukelso (BLA 761436)
Intended Pronunciation	boe saye' ah	aw kel' soe
Nonproprietary Name	denosumab-xxxx	
Indication	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	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.

n for Bosaya***. Cambridge (MA): Biocon Biologics Inc.; 2024 Sep 16. Available 61436\0001\m1\us\114-labeling\draft\labeling\draft-labeling-text-pls-clean.doc.

Table 3. Relevant Product Information for Bosaya*** and Aukelso		
Product Name	Bosaya*** (BLA 761436)[I]	Aukelso (BLA 761436)
	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	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. Hypercalcemia of Malignancy: 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

The Applicant did not provide a rationale of the proposal to use a dual proprietary name for this product. However, we note that US-licensed Reference Products, Prolia and Xgeva (BLA 125320), also use a dual proprietary naming strategy.

We have evaluated the risks associated with the proposed dual proprietary name strategy and do not object to the use of a dual proprietary name in this case.

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On March 26, 2025, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Aukelso, is conditionally acceptable.

3.1 COMMENTS TO BIOCON BIOLOGICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 10, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.[m]

Table 4. 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.

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

Table 4. 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 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, Purple Book, 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 (Tables 4-6) 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 that 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 4).
- 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[n]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[n] 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

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 OPQ 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 Safety Evaluator 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 5. 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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?	

Table 6: 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	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 as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 7. 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. Aukelso Study (Conducted on 1/24/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: Aukelso 120 mg subq today Aukelso Inject 120 mg Sub-Q Q4 weeks #1 vial Outpatient Prescription:	Aukelso Inject 120 mg subcutaneously every 4 weeks Dispense 1 vial
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Aukelso	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Aukelso People Received Study: 167 People Responded: 101					
Total	26	27	20	28	101
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
AHKELSO	0	0	2	0	2
AKELSO	0	0	1	0	1
ALCELSO	0	0	1	0	1
ALKELSO	0	0	2	0	2
ANKELSO	1	0	0	0	1
AQELSO	0	0	1	0	1
AUBELSO	0	1	0	0	1
AUKEBO	2	0	0	0	2
AUKELAO	1	0	0	0	1
AUKELSO	21	25	5	28	79
AULELSO	1	0	0	0	1
AUTELSO	0	1	0	0	1
AWKELSO	0	0	1	0	1
OBKELSO	0	0	1	0	1
OCELSO	0	0	1	0	1
OLCASO	0	0	1	0	1
OLKELSIVO	0	0	1	0	1
OPKELSO	0	0	1	0	1
OUKELSO	0	0	1	0	1

OVKELZO	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Aukelso Pronunciation: aw kel' soe Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg subcutaneously every 4 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Aukelso	100	This name is the subject of this review.
2.	(b) (4) ***	70	Proposed proprietary name for IND 115333 found to be unacceptable by DMEPA due to a conflict with a marketed product (OSE # 2016-10674485 dated 03/08/2017). BLA 761082 approved on 02/25/2022 under the proprietary name, Releuko.

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.	Lokelma	55

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: Aukelso Pronunciation: aw kel' soe Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg subcutaneously every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	(b) (4) ***	60	(b) (4)

No.	Proposed name: Aukelso Pronunciation: aw kel' soe Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg subcutaneously every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	(b) (4) **	59	(b) (4)
3.	Ak-Sulf	58	This name pair has sufficient orthographic and phonetic differences.
4.	Aemcolo	57	This name pair has sufficient orthographic and phonetic differences.
5.	Alkets	57	This name pair has sufficient orthographic and phonetic differences.
6.	Austedo	56	This name pair has sufficient orthographic and phonetic differences.
7.	Qalsody	56	This name pair has sufficient orthographic and phonetic differences.
8.	Asepso	55	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4) ***	52	See FMEA in Section 2.2.4
10.	Okebo	47	See FMEA in Section 2.2.4

No.	Proposed name: Aukelso Pronunciation: aw kel' soe Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg subcutaneously every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
11.	Ocella	44	See FMEA in Section 2.2.4

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Koselugo	53
2.	Aquasol E	48

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) **	58	(b) (4)
2.	(b) (4) ***	58	Proposed proprietary name for NDA 214047 found unacceptable by DMEPA due to misbranding (OSE# 2020-39265758 dated May 12, 2020). NDA 214047 approved under the proprietary name Thyquidity.
3.	Codelsol	56	International product formerly marketed in Turkey.
4.	(b) (4) ***	56	Proposed proprietary name for IND 147005 was found conditionally acceptable on January 23, 2024 but was withdrawn by Sponsor on May 31, 2024. Proprietary name Tryptyr*** was submitted under corresponding NDA 217370 and was found conditionally acceptable on August 19, 2024.
5.	(b) (4) ***	55	Proposed proprietary name for NDA 214047 found unacceptable by DMEPA due to misbranding (OSE# 2020-

No.	Name	POCA Score (%)	Failure preventions
			37621867 dated March 30, 2020). NDA 214047 approved under the proprietary name Thyquidity.

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	58
2.	Elelyso	56

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

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/s/

AMY J BAO
03/26/2025 02:22:24 PM

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03/26/2025 02:31:05 PM

IDALIA E RYCHLIK
03/27/2025 10:55:30 AM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 3, 2024
Application Type and Number:	BLA 761436
Product Name, Dosage Form, and Strength:	(b) (4) (denosumab-xxxx)[a] injection, 120 mg/1.7 mL (70 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2024-1044726006
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder denosumab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

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/s/

AMY J BAO
12/03/2024 03:20:51 PM

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MISHALE P MISTRY on behalf of IDALIA E RYCHLIK
12/04/2024 11:00:48 AM
Signed on behalf of Idalia Rychlik

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:	November 21, 2024
Application Type and Number:	BLA 761436
Product Name, Dosage Form, and Strength:	Bosaya (denosumab-xxxx)[a] injection, 60 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2024-1044725987
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder denosumab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Bosaya, 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. Biocon submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 16, 2024[c] and the prescribing information received on September 16, 2024.[d]

Table 1. Relevant Product Information for Bosaya	
Intended pronunciation:	boe saye' ah
Nonproprietary name:	denosumab-xxxx
Indication:	• 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
Dosage Form:	injection
Strength:	60 mg/mL
Route of administration:	Subcutaneous
Dose and frequency:	60 mg every 6 months
How Supplied:	Single-dose prefilled syringe with a safety guard

[b] Proprietary Name Safety Summary for Bosaya. [redacted] (b) (4) .; 2024 Aug 27. Available from: \\CDSESUB1\evsprod\BLA761436\0001\m1\us\118-proprietary-names\annexure-1-proprietary-name-assessment-report-bosaya.pdf.

[c] Request for Proprietary Name Review (Bosaya, BLA 761436). Cambridge (MA): Biocon Biologics Inc.; 2024 Sep 16. Available from: \\CDSESUB1\evsprod\BLA761436\0001\m1\us\118-proprietary-names\request-for-proprietary-name-review.pdf.

[d] Proposed prescribing information for Bosaya. Cambridge (MA): Biocon Biologics Inc.; 2024 Sep 16. Available from: \\CDSESUB1\evsprod\BLA761436\0001\m1\us\114-labeling\draft\labeling\draft-labeling-text-pfs-clean.doc.

Table 1. Relevant Product Information for Bosaya	
Storage:	Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Prior to administration, it may be allowed to reach room temperature (up to 25°C/77°F) in the original container. Once removed from the refrigerator, it must not be exposed to temperatures above 25°C/77°F and must be used within 30 days. If not used within the 30 days, it should be discarded. Do not use after the expiry date printed on the label. Protect from direct light and heat. Avoid vigorous shaking
Reference Product:	Bosaya (denosumab-xxxx) is a proposed interchangeable to US-licensed Reference Product, Prolia (denosumab) BLA 125320

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bosaya 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 Bosaya. The Division of General Endocrinology (DGE) did not comment on the findings of OPDP's assessment for Bosaya.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Biocon did not provide a derivation or intended meaning for the proposed proprietary name, Bosaya, in their submission. This proprietary name is comprised of a single word that contains the letter strings "OS" and "SA", which are medical abbreviations for "left eye" and "sustained action", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviations "OS" and "SA" in the middle of the proposed proprietary name, Bosaya, makes it unlikely for the "OS" and "SA" letter strings to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the "OS" and "SA" letter strings in this case.

[e] USAN stem search conducted on November 12, 2024.

Beyond these noted abbreviations, we note that Bosaya does not contain any additional components (i.e., dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Bosaya at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (84) practitioners participated in DMEPA's prescription studies for Bosaya.

One respondent in the Verbal study misinterpreted the proposed proprietary name as "Vosea", which is a direct hit of the marketed product Vosea (metoclopramide). However, we identified Vosea as an international product marketed in Indonesia (see Appendix G).

The remaining responses did not overlap with any currently marketed products, nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[f] identified 21 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search, FDA Prescription Simulation Study, and [redacted] (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	18
Low similarity name pair: combined match percentage score ≤54%	7

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 27 names contained in Table 2 determined none of the names will pose a risk for confusion with Bosaya as described in Appendices C through H.

[f] POCA search conducted on November 12, 2024 in version 5.9.

2.2.8 DISCUSSION OF DUAL PROPRIETARY NAME

Biocon intends to market denosumab-xxxx under two different proprietary names: Bosaya (BLA 761436) and (b) (4) *** (BLA 761436). Table 3 compares the two proposed proprietary names and their respective product characteristics.

Table 3. Relevant Product Information for Bosaya and (b) (4) ***		
Product Name	Bosaya (BLA 761436)	(b) (4) *** (BLA 761436)[g]
Intended Pronunciation	boe saye' ah	(b) (4)
Nonproprietary Name	denosumab-xxxx	
Indication	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	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.
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:

[g] Proposed prescribing information for (b) (4) ***. Cambridge (MA): Biocon Biologics Inc.; 2024 Sep 16. Available from: \\CDSESUB1\evsprod\BLA761436\0001\m1\us\114-labeling\draft\labeling\draft-labeling-text-vial-clean.doc.

Table 3. Relevant Product Information for Bosaya and (b) (4) ***		
Product Name	Bosaya (BLA 761436)	(b) (4) *** (BLA 761436)[g]
		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. Hypercalcemia of Malignancy: 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	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

de a rationale of the proposal to use a dual proprietary name for this
that US-licensed Reference Products, Prolia and Xgeva (BLA 125320), also use a dual proprietary naming strategy.

We have evaluated the risks associated with the proposed dual proprietary name strategy and do not object to the use of a dual proprietary name in this case.

APPEARS THIS WAY ON ORIGINAL

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On November 21, 2024, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Bosaya, is conditionally acceptable.

3.1 COMMENTS TO BIOCON BIOLOGICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 16, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 4*. 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.[h]

*Table 4. 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.

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

*Table 4. 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 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, Purple Book, 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 5-7) 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 5).
- 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[i]. 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 6).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 7) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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-

[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

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 OPQ 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 Safety Evaluator 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 5. 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?		

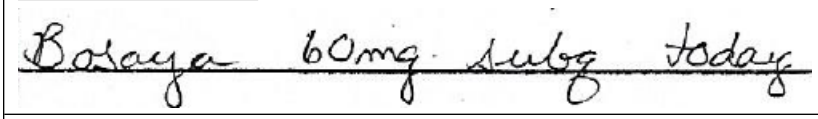
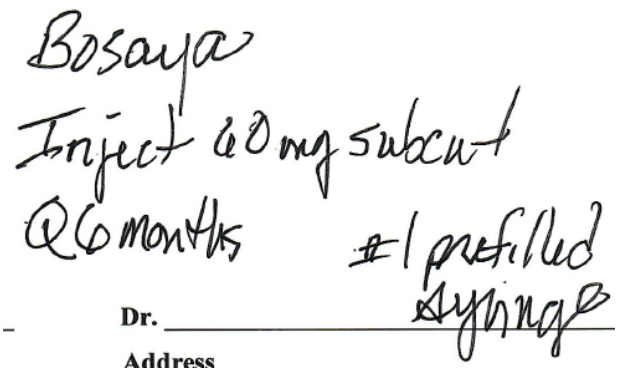
<table>
<tr><th colspan="3">Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

Table 7. 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. Bosaya Study (Conducted on 9/27/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Bosaya Inject 60 mg subQ once every 6 months Dispense 1 prefilled syringe
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Bosaya	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Bosaya People Received Study: 187 People Responded: 84					
Total	21	19	21	23	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BORAYA	1	0	0	0	1
BOSAYA	20	19	1	23	63
BOSEA	0	0	2	0	2
BOSEYA	0	0	1	0	1
BOSSEYA	0	0	1	0	1
OCEA	0	0	1	0	1
OSAYA	0	0	6	0	6
OSEA	0	0	3	0	3
OSEAH	0	0	2	0	2
OSEYA	0	0	2	0	2
OSSEYA	0	0	1	0	1
VOSEA	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Bosaya Pronunciation: boe saye' ah Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg subcutaneously 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.	Bosaya	100	This name is the subject of this review.
2.	(b) (4) ***	77	(b) (4)

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 – 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: Bosaya Pronunciation: boe saye' ah Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg subcutaneously 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.	(b) (4) ***	64	(b) (4)

No.	Proposed name: Bosaya Pronunciation: boe saye' ah Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg subcutaneously 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)
2.	Byfavo	61	This name pair has sufficient orthographic and phonetic differences.
3.	Biogaia	59	This name pair has sufficient orthographic and phonetic differences.
4.	Buspar	57	This name pair has sufficient orthographic and phonetic differences.
5.	Bonsity	56	This name pair has sufficient orthographic and phonetic differences.
6.	Bifera	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.	Boniva	54

No.	Name	POCA Score (%)
2.	Bosulif	54
3.	Baby Gas	52
4.	Bayrab	51
5.	Bosentan	50
6.	Bisacodyl	46
7.	Bonjesta	46

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.	Vosea	64	See FMEA in Section 2.2.4
2.	(b) (4) ***	62	(b) (4)
3.	Boscalid	56	Product is not a drug. It is a fungicide used in agriculture.
4.	(b) (4) ***	62	Proposed proprietary name for IND 116327 found unacceptable by DMEPA (OSE# 2018-25027154 dated 12/27/2018). BLA 761156 approved under the proprietary name Sogroya.

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

No.	Name	POCA Score (%)
1.	Cosela	59
2.	Nasal La	59

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

No.	Name	POCA Score (%)
3.	Potaba	59
4.	Savaysa	58
5.	Tosymra	58
6.	Dofsol-A	56
7.	Today	56
8.	Vostally***	56

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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