CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761398Orig1s000
761398Orig2s000

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:	12/20/2024
Responsible OND Division:	Division of General Endocrinology (DGE)
Application Type and Number:	BLA 761398
Product Name and Strength:	Conexxence (denosumab-bnht) injection, 60 mg/mL Bomyntra (denosumab-bnht) injection 120 mg/1.7 mL (70 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Fresenius Kabi USA, LLC (Fresenius)
FDA Received Date:	March 25, 2024
Nexus NPNS ID #:	2024-243
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 Fresenius for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761398.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On March 25, 2024, Fresenius submitted a list of ten suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Fresenius also provided findings from an external study conducted by the (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Fresenius:

Table 1. Suffixes submitted by Fresenius***

1.	bnht
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for Nonproprietary Naming - Suffixes BLA 761398. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2024 Mar 25. Available from: \\CDSESUB1\EVSPROD\bla761398\0001\m1\us\118-prop-names\request-for-nonproprietary-naming-suffixes.pdf

[b] Request for Nonproprietary Naming – Suffixes – Safety Report BLA 761398. (b) (4) (b) (4); 2024 Mar 25. Available from: \\CDSESUB1\EVSPROD\bla761398\0001\m1\us\118-prop-names\request-for-nonproprietary-naming-suffixes-safety-report.pdf

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

2.1 denosumab-bnht

Fresenius's first proposed suffix, -bnht, is comprised of 4 distinct letters.

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

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On December 18, 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 December 20, 2024.

4 CONCLUSION

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

4.1 Recommendations for Fresenius Kabi USA, LLC

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

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

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

/s/

CARLOS M MENA-GRILLASCA
12/20/2024 12:56:43 PM

MISHALE P MISTRY
12/23/2024 02:31:59 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:	June 13, 2024
Application Type and Number:	BLA 761398
Product Name, Dosage Form, and Strength:	Bomyntra (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:	Fresenius Kabi USA, LLC (Fresenius Kabi)
PNR ID #:	2024-1044725721
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, Bomyntra, 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. Fresenius Kabi submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Fresenius Kabi previously submitted the proposed proprietary name, [redacted] (b) (4) *** under IND 145897 on June 16, 2023. However, on December 12, 2023, we found the name, [redacted] (b) (4) *** unacceptable due to misbranding concerns.[c]

Thus, Fresenius Kabi submitted the proposed proprietary name, Bomyntra, for review on March 25, 2024 under BLA 761398.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 25, 2024[d] and the prescribing information received on March 25, 2024[e].

Table 1. Relevant Product Information for Bomyntra	
Intended pronunciation:	boe min' trah
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.

[b] Proprietary Name Safety Summary for BOMYNTRA. [redacted] (b) (4) 2024 Feb 28. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\118-prop-names\proprietary-name-safety-summary-bomyntra.pdf

[c] Rahbani, P. Proprietary Name Review for [redacted] (b) (4) *** (IND 145897). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Dec 12. PNR ID No. 2023-1044725192.

[d] Request for Proprietary Name Review for Bomyntra. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2024 Mar 25. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\118-prop-names\proprietary-name-request-bomyntra.pdf

[e] Proposed prescribing information for Bomyntra. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2024 Mar 25. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\114-labeling\114a-draft-label\draft-labeling-text-uspi-120-mg-vial-and-pfs.docx

Table 1. Relevant Product Information for Bomyntra	
Dosage Form:	injection
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 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, single-dose prefilled syringe
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 or direct light and must be used within 30 days. Discard if not used within the (b) (4) days. Do not use after the expiry date printed on the label. Protect from direct light and heat. Avoid vigorous shaking.
Reference Product:	Bomyntra (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, Bomyntra.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bomyntra 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 Bomyntra. The Division of General Endocrinology (DGE) concurred with the findings of OPDP's assessment for Bomyntra.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Fresenius Kabi did not provide a derivation or intended meaning for the proposed proprietary name, Bomyntra, in their submission. This proprietary name is comprised of a single word that contains the medical abbreviations for "time release" (i.e., "TR") and "tramadol" (i.e., "TRA") within the name. Although we typically discourage the incorporation of medical abbreviations in proprietary names, we determined that the location of the abbreviation "tr" within the proposed proprietary name is unlikely to be separated from the surrounding letters in a manner that could lead to a medication error. Additionally, we note the letters "tra" at the end of a proprietary name is common in drug nomenclature for currently marketed drug products (e.g., Amvuttra, Fylnetra, Inflectra, etc.). Thus, we do not object to the inclusion of the abbreviations "tr" and "tra" in this case. There were no additional components of the name that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On May 2, 2024, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Bomyntra at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-six (86) practitioners participated in DMEPA's prescription simulation studies for Bomyntra.

One respondent in the verbal study misinterpreted the proposed proprietary name as "Omintra", which sounds similar to the marketed name, Omidria (phenylephrine and ketorolac). We evaluated the name pair, Bomyntra and Omidria further and find that they have sufficient orthographic and phonetic differences. This is supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates a combined score of 50%, orthographic score of 53%, and phonetic score of 48%, indicating low similarity. Additionally, there are multiple product characteristic differences between Bomyntra and Omidria. The products differ in dosage form (injection versus solution), route of administration (subcutaneous versus intraocular), and frequency (every 4 weeks versus as needed for surgical procedures). Thus, we find the name pair has sufficient orthographic, phonetic, and product characteristic differences, and Omidria 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.

[f] USAN stem search conducted on May 16, 2024.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[g] identified 83 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 (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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	77
Low similarity name pair: combined match percentage score ≤54%	9

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

Our analysis of the 89 names contained in Table 2 determined none of the names will pose a risk for confusion with Bomyntra as described in Appendices C through H.

2.2.8 DISCUSSION OF DUAL PROPRIETARY NAME

Fresenius Kabi intends to market denosumab under two different proprietary names: Conexxence*** (BLA 761398) and Bomyntra (BLA 761398). Table 3 compares the two proposed proprietary names and their respective product characteristics.

Table 3. Relevant Product Information for Conexxence*** and Bomyntra		
Product Name	Conexxence***	Bomyntra
Initial Approval Date	N/A	N/A
Intended Pronunciation	kon ex' ens	boe min' trah
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.

[g] POCA search conducted on May 7, 2024 in version 5.8.

Table 3. Relevant Product Information for Conexxence*** and Bomyntra		
Product Name	Conexxence***	Bomyntra
	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. 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

Table 3. Relevant Product Information for Conexxence*** and Bomyntra		
Product Name	Conexxence***	Bomyntra
		120 mg/1.7 mL single-dose prefilled syringe, 1 syringe 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

APPEARS THIS WAY ON ORIGINAL

ntain the same active ingredients, they have different indications, supplied in different presentations (see Table 3). We note that the 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.[h] However, given these products will have different indications, strengths, dosages, and presentations, 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 June 13, 2024, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Bomyntra, 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 FRESENIUS KABI USA, LLC

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

If any of the proposed product characteristics as stated in your submission, received on March 25, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

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

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.[i]

*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.

[i] 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[j]. 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-

[j] Shah, M, Merchant, L, 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?		

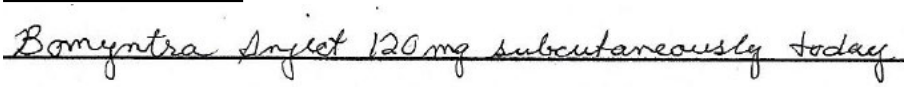
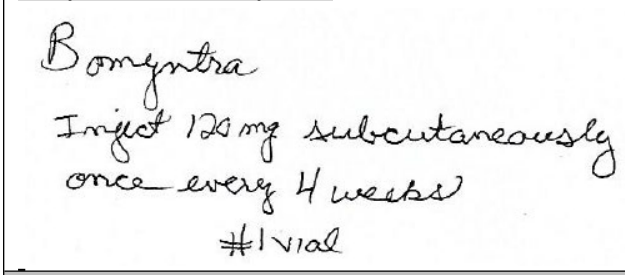
<table>
<tr><th colspan="3">Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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. Bomyntra Study (Conducted on 4/5/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Bomyntra Inject 120 mg subcutaneously once every 4 weeks Dispense 1 vial
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Bomyntra	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Bomyntra People Received Study: 173 People Responded: 86					
Total	19	24	22	21	86
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BOMENTRA	0	0	6	0	6
BOMEYUTRA	0	1	0	0	1
BOMINTRA	0	0	7	0	7
BOMYNTRA	18	21	1	21	61
BOMYRTRA	0	1	0	0	1
BOMYTRA	0	1	0	0	1
BONMENTRA	0	0	1	0	1
BONYNTRA	1	0	0	0	1
BOWMENTRA	0	0	1	0	1
BOWMINTRA	0	0	1	0	1
FOMENTRA	0	0	1	0	1
OMENTRA	0	0	1	0	1
OMINTRA	0	0	1	0	1
VALMINTRA	0	0	1	0	1
VOMENTRA	0	0	1	0	1

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

No.	Proposed name: Bomyntra Pronunciation: boe min' trah Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg every 4 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Bomyntra	100	This name is the subject of this review.
2.	(b) (4)***	74	The Applicant submitted proposed proprietary name (b) (4)*** under IND (b) (4) which was found unacceptable by DMEPA due to misbranding (OSE# 2022-1044724105 dated December 20, 2022). Subsequently, the proposed proprietary name Attruby*** was found conditionally acceptable for NDA 216540.
3.	Semintra	72	Veterinary product.

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.	Boy Butter	58

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: Bomyntra Pronunciation: boe min' trah Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Menactra	68	This name pair has sufficient orthographic and phonetic differences.
2.	Zymfentra	66	Orthographically, the name pair begins with different letters (B versus Z), and the prefixes (Bo- verses Zym-) look different when scripted. Additionally, Zymfentra contains the downstroke letter “y” in the second position as opposed to the 4th position in Bomyntra providing for additional orthographic difference. Phonetically, the first (“boe” versus “zim”) and second (“min” versus “fen”) syllables of the name pair sound different.
3.	Bontril	64	This name pair has sufficient orthographic and phonetic differences.
4.	Salyntra	64	Orthographically, the name pair begins with different letters (B versus S), and Salyntra contains an additional upstroke letter “l” in the third position which differentiates the name shapes. Phonetically, the first (“boe” versus “sa”) and beginning of the second (“min” versus “lin”) syllables of the name pair sound different. Additionally, the products differ in dosage form (injection versus gel), route of administration (subcutaneous versus topical), and frequency (every 4 weeks versus at night). These characteristics

No.	Proposed name: Bomyntra Pronunciation: boe min' trah Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
5.	Minitran	63	This name pair has sufficient orthographic and phonetic differences.
6.	Procentra	62	This name pair has sufficient orthographic and phonetic differences.
7.	Soolantra	62	This name pair has sufficient orthographic and phonetic differences.
8.	Bosentan	60	This name pair has sufficient orthographic and phonetic differences.
9.	Econtra	60	This name pair has sufficient orthographic and phonetic differences.
10.	Onzetra	60	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4) ***	60	(b) (4)

No.	Proposed name: Bomyntra Pronunciation: boe min' trah Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			Thus, in this specific case, the risk of name confusion between this name pair is minimized.
12.	Bromanate	58	This name pair has sufficient orthographic and phonetic differences.
13.	Bonjesta	56	This name pair has sufficient orthographic and phonetic differences.
14.	Bromadrine Tr	56	This name pair has sufficient orthographic and phonetic differences.
15.	Bromanyl	56	This name pair has sufficient orthographic and phonetic differences.
16.	Buminate	56	This name pair has sufficient orthographic and phonetic differences.
17.	Copiktra	56	This name pair has sufficient orthographic and phonetic differences.
18.	Fylnetra	56	This name pair has sufficient orthographic and phonetic differences.
19.	Novantrone	56	This name pair has sufficient orthographic and phonetic differences.
20.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
21.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
22.	Benlysta	55	This name pair has sufficient orthographic and phonetic differences.
23.	Broncotron	55	This name pair has sufficient orthographic and phonetic differences.
24.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Bomyntra Pronunciation: boe min' trah Established name: denosumab-xxxx Dosage form: injection Strength(s): 120 mg/1.7 mL (70 mg/mL) Dosage: 120 mg every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
25.	Dabigatran	55	This name pair has sufficient orthographic and phonetic differences.
26.	Gentran 40	55	This name pair has sufficient orthographic and phonetic differences.
27.	Kcentra	55	This name pair has sufficient orthographic and phonetic differences.
28.	Mylanta	55	This name pair has sufficient orthographic and phonetic differences.
29.	Odactra	55	This name pair has sufficient orthographic and phonetic differences.
30.	Omidria	50	See FMEA in Section 2.2.4

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

No.	Name	POCA Score (%)
1.	Mylanta Ar	54
2.	Brilinta	51
3.	Oat Bran	51
4.	Boniva	50
5.	Natroba	50
6.	Bromaline	40
7.	Brimonidine	36
8.	Simvastatin	31

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) ***	66	Proposed proprietary name withdrawn by the Applicant. NDA 208424 approved under the proprietary name, GoNitro.
2.	(b) (4) ***	66	Proposed proprietary name for IND 128177 found unacceptable by DMEPA (OSE# 2019-30983314). NDA 213426 approved under the proprietary name Seglentis.
3.	(b) (4) ***	65	Proposed proprietary name withdrawn by the Applicant. NDA 217785 approved under the proprietary name, Rezdiffra.
4.	Combantrin	62	International product marketed in Australia, Canada, Italy, and other foreign countries.
5.	Tymtran	62	Brand discontinued with no generic equivalents available. NDA 018296 withdrawn FR effective 03/02/1994.
6.	Brom Tann Pe	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Bromatan	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Bonikraft	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Femintrol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	(b) (4) ***	59	Proposed proprietary name for IND 117038 found unacceptable by DMEPA (OSE# 2017-15536632). BLA 761099 (formerly IND 117038) approved on 06/27/2019 under the proprietary name Zirabev.
11.	(b) (4) ***	59	Proposed proprietary name for IND (b) (4) found to be acceptable (b) (4) however, the application has been inactive since (b) (4).
12.	Bromanate Af	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
13.	D-Amine-Sr	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Benztrone	56	International product marketed in Italy and the UK.
15.	Bextra	56	Product withdrawn from the market due to safety concerns.
16.	Bromatapp	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
17.	Bromhist Nr	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
18.	Butatron	56	Veterinary product.
19.	(b) (4) ***	56	(b) (4)
20.	Pentran	56	International product formerly marketed in the United Kingdom.
21.	Vontrol	56	Brand discontinued with no generic equivalents available. NDA 016033 withdrawn FR effective 03/13/2009.
22.	Gentran 70	55	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[k].

No.	Name	POCA Score (%)
1.	Monit Sr	62
2.	Gonitro	60
3.	Tosymra	60
4.	Domitor	58

[k] 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 (%)
5.	Tevimbra	58
6.	Somatrem	57
7.	Fybranta	56
8.	Menostar	56
9.	Monistat	56
10.	Monistat 3	56
11.	Monistat 5	56
12.	Monistat 7	56
13.	Monistat-1	56
14.	Oby-Trim	56
15.	Sonapram	56
16.	Trumenba	56
17.	Zyban Sr	56
18.	Comirnaty	55
19.	Comirnaty 2023-2024	55
20.	Dibrom Sr	55
21.	Fentora	55
22.	Omnitrope	55
23.	(b) (4) ***	55
24.	Promacta	55
25.	Terminator	55

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/s/

AMY J BAO
06/13/2024 02:30:50 PM

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IDALIA E RYCHLIK
06/18/2024 02:11:50 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:	May 31, 2024
Application Type and Number:	BLA 761398
Product Name, Dosage Form, and Strength:	Conexxence (denosumab-xxxx)[a] injection, 60 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Fresenius Kabi USA, LLC (Fresenius Kabi)
PNR ID #:	2024-1044725698
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, Conexxence, 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. Fresenius Kabi submitted an external name study, conducted by [redacted][b], for this proposed proprietary name.

1.1 REGULATORY HISTORY

Fresenius Kabi previously submitted the proposed proprietary name, [redacted]*** under IND 145897 on June 16, 2023. However, on December 12, 2023, we found the name, [redacted]*** unacceptable due to orthographic similarities and overlapping product characteristics with the pending proprietary name, [redacted].[c]

Thus, Fresenius Kabi submitted the proposed proprietary name, Conexxence, for review on March 25, 2024 under BLA 761398.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 25, 2024[d], and the prescribing information received on March 25, 2024[e].

Table 1. Relevant Product Information for Conexxence	
Intended pronunciation:	kon ex' ens
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

[b] Proprietary Name Safety Summary for CONEXXENCE. [redacted] 2024 Mar 25. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\118-prop-names\proprietary-name-safety-summary-conexxence.pdf

[c] Rahbani, P. Proprietary Name Review for [redacted]*** (IND 145897). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Dec 12. PNR ID No. 2023-1044725193.

[d] Request for Proprietary Name Review for Conexxence (BLA 761398). Lake Zurich (IL): Fresenius Kabi USA, LLC; 2024 Mar 25. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\118-prop-names\proprietary-name-request-conexxence.pdf

[e] Proposed prescribing information for Conexxence. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2024 Mar 25. Available from: \\CDSESUB1\evsprod\BLA761398\0001\m1\us\114-labeling\114a-draft-label\draft-labeling-text-uspi-and-medication-guide-1ml-60-mg-pfs.docx

Table 1. Relevant Product Information for Conexxence	
	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 an automatic clear needle safety guard
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, product may be allowed to reach room temperature (up to 25°C/77°F) in the original container. Once removed from the refrigerator, product must not be exposed to temperatures above 25°C/77°F and must be used within (b) (4) days. If not used within (b) (4) days, product 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:	Conexxence (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, Conexxence.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Conexxence 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 Conexxence. The Division of General Endocrinology (DGE) concurred with the findings of OPDP's assessment for Conexxence.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Fresenius Kabi did not provide a derivation or intended meaning for the proposed proprietary name, Conexxence, in their submission. The proposed proprietary name, Conexxence, is comprised of a single word that contains the medical abbreviation for "extra strength" (i.e., "EX") within the name. Although we typically discourage the incorporation of medical abbreviations in proprietary names, we determined that the location of the abbreviation "ex" within the proposed proprietary name is unlikely to be separated from the surrounding letters in a manner that could lead to a medication error. Thus, we conclude that the abbreviation "ex" in the name is acceptable. There were no additional components of the name that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On May 2, 2024, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Conexxence at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-six (86) practitioners participated in DMEPA's prescription simulation studies for Conexxence. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[g] identified 50 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 the (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%	1

[f] USAN stem search conducted on May 7, 2024.

[g] POCA search conducted on May 7, 2024 in version 5.8.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	38
Low similarity name pair: combined match percentage score ≤54%	15

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

Our analysis of the 54 names contained in Table 2 determined none of the names will pose a risk for confusion with Conexxence as described in Appendices C through H.

2.2.8 DISCUSSION OF DUAL PROPRIETARY NAME

Fresenius Kabi intends to market denosumab under two different proprietary names: Conexxence (BLA 761398) and Bomyntra*** (BLA 761398). Table 3 compares the two proposed proprietary names and their respective product characteristics.

Table 3. Relevant Product Information for Conexxence and Bomyntra***		
Product Name	Conexxence	Bomyntra***
Initial Approval Date	N/A	N/A
Intended Pronunciation	kon ex' ens	boe min' trah
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	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.

Table 3. Relevant Product Information for Conexxence and Bomyntra***		
Product Name	Conexxence	Bomyntra***
	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 120 mg/1.7 mL single-dose prefilled syringe, 1 syringe 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

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ntain the same active ingredients, they have different indications, supplied in different presentations (see Table 3). 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.[h] However, given these products will have different indications, strengths, dosages, and presentations, 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 May 31, 2024, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Conexxence, 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 FRESENIUS KABI USA, LLC

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

If any of the proposed product characteristics as stated in your submission, received on March 25, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

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

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.[i]

*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.

[i] 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[j]. 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-

[j] Shah, M, Merchant, L, 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?		

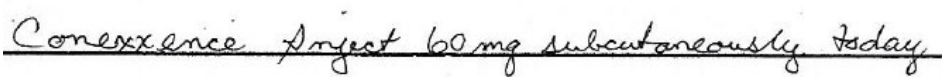
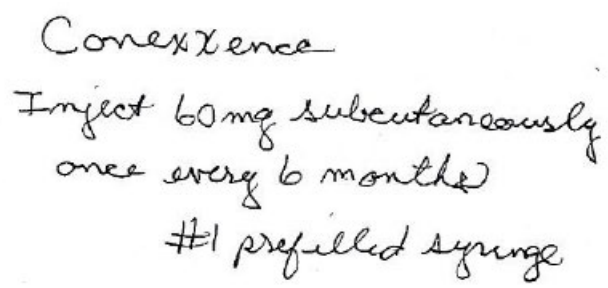
<table>
<tr><th colspan="3">Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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. Conexxence Study (Conducted on 4/5/2024)

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

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Conexxence People Received Study: 173 People Responded: 86					
Total	19	24	22	21	86
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
CONESSENCE	0	0	1	0	1
CONEXCENCE	0	0	1	0	1
CONEXENCE	0	0	2	0	2
CONEXENSE	0	0	1	0	1
CONEXINCE	0	0	1	0	1
CONEXINSE	0	0	1	0	1
CONEXSANCE	0	0	1	0	1
CONEXSENCE	0	0	1	0	1
CONEXSENSE	0	0	1	0	1
CONEXSINCE	0	0	1	0	1
CONEXUNCE	0	0	1	0	1

CONEXUS	0	0	1	0	1
CONEXXENCE	19	24	1	21	65
CONNECSENSE	0	0	1	0	1
CONNEXANCE	0	0	1	0	1
CONNEXSENCE	0	0	1	0	1
CONNEXSIS	0	0	1	0	1
CORNEXSINS	0	0	1	0	1
HONEXUSS	0	0	1	0	1
KONECYN PREFILLED SYRINGE	0	0	1	0	1
KONEXSINCE	0	0	1	0	1

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

No.	Proposed name: Conexxence Pronunciation: kon ex' ens Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg 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.	Conexxence	100	This name is the subject of this review.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Consensi	58
2.	Copaxone	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: Conexxence Pronunciation: kon ex' ens Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg 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) ***	61	This name pair has sufficient orthographic and phonetic differences.
2.	Onexton	59	This name pair has sufficient orthographic and phonetic differences.
3.	Avonex Pen	58	This name pair has sufficient orthographic and phonetic differences.
4.	Conex	58	Orthographically, the name pair differs significantly in length (10 letters vs 5 letters).

No.	Proposed name: Conexxence Pronunciation: kon ex' ens Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg 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
			Phonetically, Conexxence contains an additional third syllable, “ens”, which provides differentiation. Additionally, the products differ in dosage form (injection versus tablets or solution), route of administration (subcutaneous versus oral), frequency (every 6 months versus every 4-6 hours as needed), and indication (osteoporosis versus cold and allergy symptoms). These characteristics may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
5.	Nexiclon Xr	58	This name pair has sufficient orthographic and phonetic differences.
6.	Protex Balance	58	This name pair has sufficient orthographic and phonetic differences.
7.	Senexon S	58	Orthographically, the name pair differs in length (10 letters versus 8 letters). Senexon S also contains the “S” modifier, which provides additional orthographic differentiation if included on a prescription. Phonetically, the first syllables (“kon” versus “sen”) sound different. The modifier for Senexon S also provides an additional fourth syllable, “ess”, if included when spoken. Additionally, the products differ in dosage form (injection versus tablets), route of administration (subcutaneous versus oral), frequency (every 6 months versus

No.	Proposed name: Conexxence Pronunciation: kon ex' ens Established name: denosumab-xxxx Dosage form: injection Strength(s): 60 mg/mL Dosage: 60 mg 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
			once daily until bowel movements are normal), and indication (osteoporosis versus constipation). These characteristics may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
8.	Ctx3 Rinse	57	This name pair has sufficient orthographic and phonetic differences.
9.	Ctx4 Rinse	57	This name pair has sufficient orthographic and phonetic differences.
10.	Vaxneuvance	57	This name pair has sufficient orthographic and phonetic differences.
11.	Nexiclon	56	This name pair has sufficient orthographic and phonetic differences.
12.	Congestant	56	This name pair has sufficient orthographic and phonetic differences.
13.	Contac Sinus	55	This name pair has sufficient orthographic and phonetic differences.
14.	Nexterone	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.	Cognex	54
2.	Neo-Naclex	53
3.	Deconex	51
4.	Decongex-3	51

No.	Name	POCA Score (%)
5.	Cosentyx	50
6.	Nexcede	50
7.	Noxene	50
8.	Cophene-X	49
9.	Excenel	49
10.	(b) (4) ***	49
11.	Coniine	46
12.	Condylox	44
13.	Xoten-C	44
14.	Nexium	38
15.	Prednisone	32

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.	Doconexent	68	Product is not a drug. It is a mixture of fish oil and primrose oil used as a high-docosahexaenoic acid (DHA) supplement.
2.	Corn Extract	66	Product is not a drug. It is used for flavoring, in herbal remedies, and in cosmetics.
3.	(b) (4) ***	62	Proposed proprietary name for NDA 022503 found unacceptable, due to a conflict with a marketed product, by DMEPA (PNR ID# 2022-1044724529 dated 07/07/2022). NDA 022503 is approved under the established name, Metaxalone, as of 06/01/2015, and no new names have been submitted.
4.	Genexpect Pe	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Canesten Vc	58	International product marketed in the UK.
6.	Conex La	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
7.	Conex Pediatric	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Cyclodextrins	58	Product is not a drug. It is a group of cyclic oligomers broadly used in food manufacturing as food additives
9.	Canoxicabs	57	Name identified in RX Norm database. Unable to find product characteristics in commonly used drug databases.
10.	Corynoxeine	57	Product is not a drug. Corynoxeine is a natural product found in Mitragyna speciosa, Uncaria tomentosa, and other organisms.
11.	(b) (4) ***	57	Proposed proprietary name for BLA 761127 and IND 129198 found unacceptable by DMEPA (OSE# 2019-35994384 and 2019-33884038 dated 02/21/2020) due to similarity with marketed and discontinued products. BLA 761127 approved under the proprietary name, Daxxify.
12.	Canesten Af	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Cophene-X-P (Revised)	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Genexpect Sf	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
15.	Next Choice	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Clonixin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Combiflex Es	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
18.	Genexpect Dm	55	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[k].

No.	Name	POCA Score (%)
1.	Icodextrin	61
2.	Kunecatechins	58
3.	Genecof Xp	56
4.	Prodenrx Rinse	55

[k] 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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