# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761391Orig1s000

# PROPRIETARY NAME REVIEW(S)

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

## Memorandum

**From:**

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**Through:**

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**Subject:** Evaluation of the nonproprietary name for BLA 761391

Galderma Laboratories, L.P. (Galderma) is the license holder for Nemluvio (nemolizumab-ilto) injection, approved in Biologics License Application (BLA) 761390 on August 12, 2024, under Section 351(a) of the Public Health Service Act.

On December 13, 2023, Galderma submitted BLA 761391 pursuant to Section 351(a) of the Public Health Service Act for the addition of a new indication (see Appendix A for product characteristics). The PDUFA goal date to take action on BLA 761391 is December 13, 2024.

Per Galderma Reviewer's Guide for BLA 761391,[a] it was agreed with the Agency that both BLAs (761390 and 761391) would share a common Module 3 Quality, to facilitate a consolidated review. To that effect Galderma submitted the exact same content for both submissions. Therefore, the Drug Substance (DS) and Drug Product (DP) in pending BLA 761391 is the same as the DS and DP in the approved BLA 761390. Of note, pending BLA 761391 shares the same prefilled dual-chamber pen presentation with approved BLA 761390, (b) (4)

The proposed product is an interleukin-31 receptor alpha antagonist. Pending BLA 761391 proposes the same formulation, in the same dosage form, strength, route, and similar dose and frequency of administration as the approved BLA 761390. The main difference between the BLAs is the indication of use. Approved BLA 761390 is indicated for the treatment of adults with prurigo nodularis. Pending BLA 761391's proposed indication is the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older, whose disease is not adequately controlled with topical prescription therapies (b) (4). See Appendix A – Product Characteristics Comparison Table for more information.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, stating the Agency's intention to designate proper names that include four-letter distinguishing suffixes for biological products.[b] Therefore, pending BLA 761391 is within the scope of this naming guidance.

We carefully considered whether the nonproprietary name for pending BLA 761391 should include a different distinguishing suffix than that designated for approved BL'A 761390 or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating the same proper name (i.e. nevolimumab-ilto) for BLA 761391. Among the factors we have considered are the following:

1. The DS in the approved formulation (BLA 761390) is the same as the DS in pending BLA 761391.

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[a] AD Reviewer Guide Final BLA 761391 Nemluvio (nemolizumab). Dallas (TX): Galderma Laboratories, L.P.; 2023 Dec 13. Available from: \\CDSESUB1\EVSPROD\bla761391\0001\m1\us\ad-reviewer-guide-final.pdf

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

2. The DP in the approved BLA 761390 is the same as the DP in pending BLA 761391.
3. The formulation, dosage form, strength, route of administration are identical; and the dose and route of administration are similar/overlapping for pending BLA 761391 as that of the approved BLA 761390. See Appendix A – Product Characteristics Comparison Table for more information.
4. Considering that pending BLA 761391 shares the same DS and DP as the approved BLA 761390, no significant differences in immunogenicity profiles is expected.
5. Under FDA's prescription drug user fee bundling policy, a request for approval of a new indication, or a modification of a previously approved indication, should be submitted individually in a separate supplement to an approved original application.[a] Therefore, pending BLA 761391 could have been managed under a supplement to the approved BLA 761390, which would not have resulted in a change to the proper name under the approach to nonproprietary naming described in the final guidance.
6. Galderma is proposing to use the same proprietary name (Nemluvio) for both of their nemulizumab BLAs (BLA 761390 and BLA 761391). Although the proposed US Prescribing Information (USPI) for BLA 761391 is separate from that of the approved USPI for BLA 761390, (b) (4) . The naming convention of using the same proprietary name for different indications is not uncommon and has been found acceptable. DMEPA 1 found the proposed name Nemluvio acceptable for BLA 761390, and conditionally acceptable for pending BLA 761391.[b]

As noted in the final Nonproprietary Naming of Biological Products guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a manufacturing lot or manufacturing site for a

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

[b] Patel, M. Proprietary Name Review for Nemluvio (BLA 761390 and BLA 761391). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 7. PNR ID No. 2023-1044725511 and 2023-1044725514.

particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. As noted above, the DS and DP proposed in BLA 761391, nemolizumab-xxxx, is same as the DS and DP in approved BLA 761390. Also, as noted above, Galderma is the license holder for BLA 761390 and the applicant for BLA 761391.

Given the above factors, a different nonproprietary name for BLA 761391 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761391 could create confusion and would not further the goals of the naming convention.

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving the same nonproprietary name for BLA 761391.[a] We based this determination upon consideration of all the factors outlined above. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name format for this BLA.

The following will be communicated to Galderma in an advice letter.

Comments for Galderma:

We have determined that nemolizumab-ilto will be the proper name designated in the license should your 351(a) be approved during this review cycle.

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

Appendix A - Product Characteristics Comparison Table

| **Proprietary Name** | Nemluvio | Nemluvio |
|---|---|---|
| **Application No.** | BLA 761390 | BLA 761391 |
| **Initial Approval/ PDUFA Goal** | Approval<br>August 12, 2024 | PDUFA goal date<br>December 13, 2024 |
| **Active Ingredient** | nemolizumab-ilto | nemolizumab-xxxx |
| **Indication** | The treatment of adults with prurigo nodularis. | The treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older, whose disease is not adequately controlled with topical prescription therapies (b) (4) |
| **Route of Administration** | Subcutaneous | |
| **Dosage Form** | For Injection | |
| **Strength** | 30 mg | |
| **Dose and Frequency** | Adult patients weighing less than 90 kg: Initial dose of 60 mg (two 30 mg injections), followed by 30 mg every 4 weeks.<br>Adult patients weighing 90 kg or more: Initial dose of 60 mg (two 30 mg injections), followed by 60 mg every 4 weeks. | • Initial dose of 60 mg (two 30 mg injections), followed by 30 mg every 4 weeks.<br>• After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a dosage of 30 mg every 8 weeks is recommended. |
| **How Supplied** | single-dose prefilled dual chamber pen | • single-dose prefilled dual chamber pen<br>(b) (4) |
| **Storage** | (b) (4) | |

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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.**

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/s/

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CARLOS M MENA-GRILLASCA
11/15/2024 07:58:07 AM

MISHALE P MISTRY
11/15/2024 02:31:52 PM

GERALD J DALPAN
11/15/2024 05:30:43 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 7, 2024 |
| Application Type and Number: | BLA 761390 and BLA 761391 |
| Product Name, Dosage Form, and Strength: | Nemluvio (nemolizumab-xxxx)[a] injection, 30 mg/0.49 mL |
| Product Type: | Combination Product (Biologic-Device) |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Galderma Laboratories, L.P. (Galderma) |
| PNR ID #: | 2023-1044725511 (BLA 761390)<br>2023-1044725514 (BLA 761391) |
| DMEPA 1 Safety Evaluator: | Madhuri R. Patel, PharmD |
| DMEPA 1 Team Leader: | Yevgeniya Kogan, PharmD, BCSCP |
| DMEPA 1 Director: | Mishale Mistry, PharmD, MPH |

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder nemolizumab-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, Nemluvio, 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. Galderma submitted an external name study, conducted by [redacted][b], for this proposed proprietary name. The submitted external name study was previously reviewed under IND 117122 (see Section 1.1 below).

### 1.1 REGULATORY HISTORY

Galderma previously submitted the proposed proprietary name, Nemluvio, under IND 117122 on November 21, 2022, and we found the name conditionally acceptable on February 9, 2023.[c]

Thus, Galderma submitted the proposed proprietary name, Nemluvio, for review on December 14, 2023 under BLA 761390 and on December 15, 2023 under BLA 761391.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the prescribing information received on December 12, 2023[d] and December 13, 2023[e,f].

| **Table 1. Relevant Product Information for Nemluvio** | |
|---|---|
| **Intended pronunciation:** | nem-LUV-ee-oh |
| **Nonproprietary name:** | nemolizumab-xxxx |
| **Indication:** | **BLA 761390**<br>Treatment of prurigo nodularis<br><br>**BLA 761391**<br>Treatment of moderate-to-severe atopic dermatitis (AD) in patients ≥12 years old, who are inadequately controlled by topical therapies [redacted]. |
| **Dosage Form:** | injection |

[redacted]

[c] Vee, S. Proprietary Name Review for Nemluvio (IND 117122). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 FEB 09. PNR ID No. 2022-1044724851.

[d] Proposed prescribing information for Nemluvio. Dallas (TX): Galderma Laboratories, L.P.; 2023 DEC 12. Available from: \\CDSESUB1\EVSPROD\bla761390\0001\m1\us\draft-labeling-text.pdf.

[e] Proposed prescribing information for Nemluvio. Dallas (TX): Galderma Laboratories, L.P.; 2023 DEC 13. Available from: \\CDSESUB1\EVSPROD\bla761391\0001\m1\us\draft-labeling-text.pdf.

[redacted]

<table>
<tr><th colspan="2">Table 1. Relevant Product Information for Nemluvio</th></tr>
<tr><td>Strength:</td><td>30 mg/0.49 mL</td></tr>
<tr><td>Route of administration:</td><td>subcutaneous</td></tr>
<tr><td>Usual dosage and frequency:</td><td>BLA 761390<br><u>Age 18 years and older weighing less than 90 kg:</u><br>60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks<br><br><u>Age 18 years and older weighing 90 kg or more:</u><br>60 mg (two 30 mg injections), followed by 60 mg given every 4 weeks<br><br>BLA 761391<br><u>Age 12 years and older:</u><br>60 mg (two 30 mg injections), followed by 30 mg given every 4 weeks. After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a dosage of 30 mg (b) (4)</td></tr>
<tr><td>How Supplied:</td><td>sterile, preservative-free, white lyophilized powder available in single-dose, dual-chamber, prefilled pen (b) (4) containing nemolizumab-xxxx in one chamber and the diluent, Water for Injection, in the other chamber. (b) (4)<br><br>Each carton contains:<br>• 1 single-dose pre-filled pen, (b) (4) (b) (4)<br><table><tr><th>Presentation</th><th>Pack size</th><th>NDC #</th></tr><tr><td colspan="3">(b) (4)</td></tr><tr><td>Pre-filled Pen</td><td>Pack of 1 pen</td><td>0299-6220-15</td></tr><tr><td colspan="3">(b) (4)</td></tr></table></td></tr>
</table>

| Table 1. Relevant Product Information for Nemluvio | |
|---|---|
| **Storage:** | (b) (4) |

## 2 DISCUSSION

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nemluvio 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 Nemluvio. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Nemluvio.

### 2.2 SAFETY ASSESSMENT

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

#### 2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

#### 2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Galderma did not provide a derivation or intended meaning for the proposed proprietary name, Nemluvio, in their submission. This proprietary name is comprised of a single word.

[g] USAN stem search conducted on February 15, 2024.

Nemluvio contains the letter string '-ml-', a medical abbreviation for 'milliliters' which was evaluated in our previous review.[h] After evaluating the risks associated with the inclusion of this medical abbreviation, we do not have any objection to the inclusion of the '-ml-' letter string and we maintain our previous decision.

Beyond this abbreviation, we note that Nemluvio does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

### 2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On January 31, 2024, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Nemluvio at the initial phase of the review.

### 2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (n=84) practitioners participated in DMEPA's prescription simulation studies for Nemluvio. 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[i] identified 38 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. Since our previous review under IND 117122, we note that the proposed indications have changed from "(b) (4) to "Treatment of prurigo nodularis" (BLA 761390) and "Treatment of moderate-to-severe atopic dermatitis (AD) in patients ≥12 years old, who are inadequately controlled by topical therapies (b) (4)" (BLA 761391). We also note that in addition to the previously reviewed dose of 60 mg loading dose, followed by 30 mg every 4 weeks, there are additional maintenance dosing regimens of 60 mg every 4 weeks (BLA 761390) and 30 mg every 8 weeks (BLA 761391). We considered these changes in our re-evaluation of the name. We agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two names not previously analyzed. These names are included in Table 2 below.

[h] Vee, S. Proprietary Name Review for Nemluvio (IND 117122). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 FEB 09. PNR ID No. 2022-1044724851.

[i] POCA search conducted on February 15, 2024 in version 5.5.

### 2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

| Table 2. Names Retrieved for Review Organized by Name Pair Similarity | |
|---|---|
| Similarity Category | Number of Names |
| Highly similar name pair:<br>combined match percentage score ≥70% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 2 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 0 |

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

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

### 2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 7, 2024, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

## 3 CONCLUSION

The proposed proprietary name, Nemluvio, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at (240) 402-4156.

### 3.1 COMMENTS TO GALDERMA LABORATORIES, L.P.

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

If any of the proposed product characteristics as stated in your submissions, received on December 14, 2023 (BLA 761390) and December 15, 2023 (BLA 761391), 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.[j]

| *Table 3. Prescreening Checklist for Proposed Proprietary Name<br>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. |

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

| *Table 3. Prescreening Checklist for Proposed Proprietary Name<br>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 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 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[k]. 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, 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-

[k] 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 4. 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?<br>*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?<br>**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? | | |

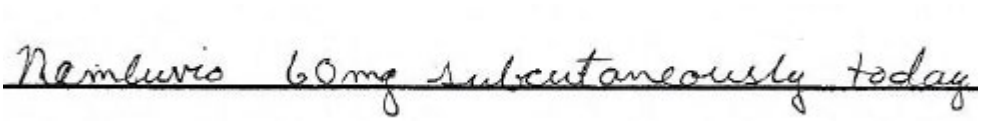
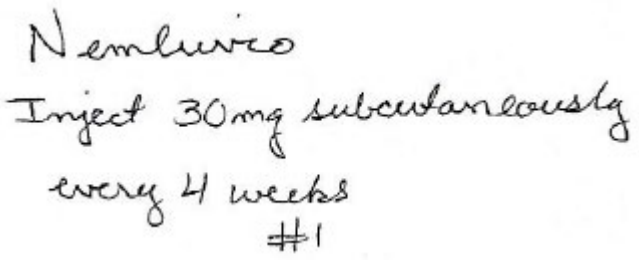
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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.<br>For single strength products, also consider circumstances where the strength may not be expressed.<br>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.<br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br>• 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.<br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br>• 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)<br>• Do the names begin with different first letters?<br>• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>• *FDA considers the length of names different if the names differ by two or more letters.<br>• 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)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

| Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).** | | |
|---|---|---|
| | placement of upstroke/downstroke letters present in the names?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | |

| Table 6. 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. Nemluvio Study (Conducted on 1/30/2024)

| Handwritten Medication Order Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Nemluvio<br>Inject 30 mg subcutaneously every 4 weeks.<br>Dispense 1 |
| Outpatient Prescription:<br>  <br> | |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font) | |
| **Nemluvio** | |

| FDA Prescription Simulation Responses (Aggregate Report) | | | | | |
|---|---|---|---|---|---|
| Study Name: Nemluvio<br>People Received Study: 165<br>People Responded: 84 | | | | | |
| Total | 18 | 25 | 16 | 25 | 84 |
| INTERPRETATION | INPATIENT | OUTPATIENT | VOICE | CPOE | TOTAL |
| NAMLEVIO | 0 | 0 | 1 | 0 | 1 |
| NAMLOVIO | 0 | 0 | 1 | 0 | 1 |
| NAMLUVIO | 6 | 0 | 0 | 0 | 6 |
| NEMBIVRO | 0 | 1 | 0 | 0 | 1 |
| NEMBRIVIO | 0 | 1 | 0 | 0 | 1 |
| NEMBUVIO | 1 | 0 | 0 | 0 | 1 |
| NEMLAVIO | 0 | 0 | 3 | 0 | 3 |
| NEMLEVIO | 0 | 0 | 1 | 0 | 1 |
| NEMLIUVIO | 0 | 1 | 0 | 0 | 1 |
| NEMLOBIO | 0 | 0 | 1 | 0 | 1 |

| | | | | | |
|---|---|---|---|---|---|
| NEMLOVIO | 0 | 0 | 7 | 0 | 7 |
| NEMLUVCO | 0 | 3 | 0 | 0 | 3 |
| NEMLUVICO | 0 | 1 | 0 | 0 | 1 |
| NEMLUVIO | 10 | 17 | 2 | 25 | 54 |
| NEWLUVICO | 0 | 1 | 0 | 0 | 1 |
| RAMLUVIS | 1 | 0 | 0 | 0 | 1 |

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

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

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

APPENDIX G. Names not likely to be confused or not used in usual practice settings for the reasons described. – N/A

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Emblaveo*** | 66 |
| 2. | Zelsuvmi*** | 57 |

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

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**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.**

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/s/

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