

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**761315Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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|                                                           |                                                                                                                              |
|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Date of This Review:                                      | September 13, 2024                                                                                                           |
| Application Type and Number:                              | BLA 761315 (b) (4)                                                                                                           |
| Product Name, Dosage Form, and Strength:                  | Alhemo (concizumab-mtci) <sup>a</sup> Injection, 60 mg/1.5 mL (40 mg/mL); 150 mg/1.5 mL (100 mg/mL); 300 mg/3 mL (100 mg/mL) |
| Product Type:                                             | Combination Product (Biologic-Device)                                                                                        |
| Rx or OTC:                                                | Prescription (Rx)                                                                                                            |
| Applicant/Sponsor Name:                                   | Novo Nordisk Inc. (Novo Nordisk)                                                                                             |
| PNR ID #:                                                 | 2024 – 1044725856 and 2024 - 1044725917                                                                                      |
| DMEPA 2 Safety Evaluator:                                 | Robbie Kattappuram, PharmD, BCPS                                                                                             |
| DMEPA 2 Team Leader:                                      | Nicole Iverson, PharmD, BCPS                                                                                                 |
| DMEPA 2 Associate Director for Nomenclature and Labeling: | Hina Mehta, PharmD                                                                                                           |

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<sup>a</sup> The nonproprietary name, concizumab-mtci, was found conditionally acceptable on August 6, 2024.

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Alhemo, 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. Novo Nordisk submitted an external name study, conducted by (b) (4), for this proposed proprietary name under BLA 761315 (b) (4). The submitted external name study was previously reviewed under IND 111691 (see Section 1.1 below). We note that the external name study POCA search results were updated with the resubmission of BLA 761315 (b) (4). There were no new names identified.

### 1.1 BACKGROUND AND REGULATORY HISTORY

Novo Nordisk previously submitted the proposed proprietary name, Alhemo, under IND 111691 on June 17, 2019, and we found the name conditionally acceptable on September 16, 2019.<sup>c</sup>

Novo Nordisk submitted the name, Alhemo, for review on August 24, 2022 as part of the marketing application for BLA 761315 and we found the name conditionally acceptable on November 18, 2022.<sup>d</sup> The application received a Complete Response (CR) letter on April 24, 2023.<sup>e</sup>

Thus, Novo Nordisk submitted a Class 2 Resubmission on June 20, 2024. (b) (4)

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name and prescribing information submission received on June 20, 2024<sup>f</sup> for BLA 761315 (b) (4)

(b) (4)

| Table 1. Relevant Product Information for Alhemo |                    |
|--------------------------------------------------|--------------------|
| Application Number                               | BLA 761315 (b) (4) |
| Intended pronunciation:                          | AI-HEE-mo          |

<sup>b</sup> Request for Proprietary Name Review (BLA 761315 Alhemo). Plainsboro (NJ): (b) (4); 2024 May 31. Available from: <\\CDSESUB1\EVSPROD\bla761315\0056\m1\us\m1-18-proprietary-name-request.pdf>.

<sup>c</sup> Mena-Grillasca, C. Proprietary Name Review for Alhemo (IND 111691). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2019 Sep 16. PNR ID No. 2019-30983272.

<sup>d</sup> Black, S. Proprietary Name Review for Alhemo (BLA 761315). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 Nov 18. PNR ID No. 2019-30983272.

<sup>e</sup> Hamilton, C on behalf of Lisa Yanoff. Complete Response for BLA 761315. Silver Spring (MD): FDA, CDER, OND, Division of Non-Malignant Hematology (DNH) (US); 2023 Apr 24.

<sup>f</sup> BLA 761315 Resubmission. Plainsboro (NJ): Novo Nordisk Inc.; 2024 Jun 20. Available from: <\\CDSESUB1\EVSPROD\bla761315\0056\m1\us\m1-2-cover-letter.pdf>.

(b) (4)

| Table 1. Relevant Product Information for Alhemo |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Nonproprietary name:                             | concizumab-mtci                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Indication:                                      | <p>Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with:</p> <ul style="list-style-type: none"> <li>• hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors</li> <li>• hemophilia B (congenital factor IX deficiency) with FIX inhibitors</li> </ul>                                                                                                                                   |
| Dosage Form:                                     | Injection                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Strength:                                        | 60 mg/1.5 mL (40 mg/mL); 150 mg/1.5 mL (100 mg/mL); 300 mg/3 mL (100 mg/mL)                                                                                                                                                                                                                                                                                                                                                                                         |
| Route of administration:                         | Subcutaneous                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose and frequency:                              | <p>Recommended dosing regimen:</p> <p>Day 1: Loading dose of 1 mg/kg</p> <p>Day 2: Once-daily dose of 0.20 mg/kg until individualization of maintenance dose</p> <p>Individualize maintenance dose once based on the following product plasma concentrations:</p> <p>&lt;200 ng/mL: adjust to a once-daily dose of 0.25 mg/kg</p> <p>200 to 4000 ng/mL: continue once-daily dose of 0.20 mg/kg</p> <p>&gt;4000 ng/mL: adjust to a once-daily dose of 0.15 mg/kg</p> |

(b) (4)

Table 1. Relevant Product Information for Alhemo

| How Supplied:             | <p>Alhemo is a clear to slightly opalescent, colorless to slightly yellow liquid, that may contain translucent to white particles (b) (4)</p> <p>Alhemo is available as one 1.5 mL or 3 mL single-patient-use prefilled pen per carton in the following presentations:</p> <table><tr><th>Presentation</th><th>Dose Button and Cartridge Holder Color Indicator</th><th>NDC Number</th></tr><tr><td>60 mg/1.5 mL (40 mg/mL)</td><td>Brown</td><td>0169-2084-15</td></tr><tr><td>150 mg/1.5 mL (100 mg/mL)</td><td>Gold</td><td>0169-2080-15</td></tr><tr><td>300 mg/3 mL (100 mg/mL)</td><td>(b) (4) white</td><td>0169-2081-03</td></tr></table> | Presentation | Dose Button and Cartridge Holder Color Indicator | NDC Number | 60 mg/1.5 mL (40 mg/mL) | Brown | 0169-2084-15 | 150 mg/1.5 mL (100 mg/mL) | Gold | 0169-2080-15 | 300 mg/3 mL (100 mg/mL) | (b) (4) white | 0169-2081-03 |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------------------------------------------|------------|-------------------------|-------|--------------|---------------------------|------|--------------|-------------------------|---------------|--------------|
| Presentation              | Dose Button and Cartridge Holder Color Indicator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | NDC Number   |                                                  |            |                         |       |              |                           |      |              |                         |               |              |
| 60 mg/1.5 mL (40 mg/mL)   | Brown                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 0169-2084-15 |                                                  |            |                         |       |              |                           |      |              |                         |               |              |
| 150 mg/1.5 mL (100 mg/mL) | Gold                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 0169-2080-15 |                                                  |            |                         |       |              |                           |      |              |                         |               |              |
| 300 mg/3 mL (100 mg/mL)   | (b) (4) white                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 0169-2081-03 |                                                  |            |                         |       |              |                           |      |              |                         |               |              |
| Storage:                  | <p>Before use: Store in a refrigerator at 36°F to 46°F (2°C to 8°C) for up to 24 months.</p> <p>After first use: Store for up to 4 weeks in a refrigerator at 36°F to 46°F (2° to 8°C) or at room temperature below 86°F (30°C).</p>                                                                                                                                                                                                                                                                                                                                                                                                              |              |                                                  |            |                         |       |              |                           |      |              |                         |               |              |

## 2 DISCUSSION

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Alhemo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Alhemo. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Alhemo.

### 2.2 SAFETY ASSESSMENT

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

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

There is no USAN stem present in the proposed proprietary name.<sup>h</sup>

#### 2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

<sup>h</sup> USAN stem search conducted on July 8, 2024.

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 July 8, 2024, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Alhemo at the initial phase of the review.

### 2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-one (n= 91) practitioners participated in DMEPA's prescription simulation studies for Alhemo. 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<sup>i</sup> identified 31 names with a combined score of  $\geq 55\%$  or an individual orthographic or phonetic score of  $\geq 70\%$ . We 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. We also evaluated previously identified names taking into account the change in product characteristics:

|                                             |
|---------------------------------------------|
| Table 2. Changes in Product Characteristics |
|---------------------------------------------|

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<sup>i</sup> POCA search conducted on July 8, 2024 in version 5.9.

| Table 2. Changes in Product Characteristics |                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                               |         |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
|                                             | Alhemo (previous BLA 761315 submission)                                                                                                                                                                                                                                                                                       | Alhemo (current BLA 761315 submission)                                                                                                                                                                                                                                                                                        | (b) (4) |
| Indication:                                 | <p>Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with:</p> <ul style="list-style-type: none"> <li>hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors</li> <li>hemophilia B (congenital factor IX deficiency) with FIX inhibitors</li> </ul> | <p>Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with:</p> <ul style="list-style-type: none"> <li>hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors</li> <li>hemophilia B (congenital factor IX deficiency) with FIX inhibitors</li> </ul> |         |
| Strength:                                   | <div>(b) (4)</div> <p>60 mg/1.5 mL (40 mg/mL), 150 mg/1.5 mL (100 mg/mL), and 300 mg/3 mL (100 mg/mL)</p>                                                                                                                                                                                                                     | <p>60 mg/1.5 mL (40 mg/mL); 150 mg/1.5 mL (100 mg/mL); 300 mg/3 mL (100 mg/mL)</p>                                                                                                                                                                                                                                            |         |

| Table 2. Changes in Product Characteristics |                                                                                                                                                                                                                                                                |                                                  |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| How Supplied:                               | Alhemo is a clear to slightly opalescent, colorless to slightly yellow liquid, that may contain translucent to white particles (b) (4). Product is available as one 1.5 mL or 3 mL single patient use prefilled pen per carton in the following presentations: |                                                  |
|                                             | Presentation                                                                                                                                                                                                                                                   | Dose Button and Cartridge Holder Color Indicator |
|                                             | (b) (4)                                                                                                                                                                                                                                                        |                                                  |
|                                             | 60 mg/1.5 mL (40 mg/mL)                                                                                                                                                                                                                                        | brown                                            |
|                                             | 150 mg/1.5 mL (100 mg/mL)                                                                                                                                                                                                                                      | gold                                             |
|                                             | 300 mg/3 mL (100 mg/mL)                                                                                                                                                                                                                                        | (b) (4)                                          |
|                                             |                                                                                                                                                                                                                                                                |                                                  |

|                                                                                                                                                                                                                                                               |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| Alhemo is a clear to slightly opalescent, colorless to slightly yellow liquid, that may contain translucent to white particles (b) (4). Alhemo is available as one 1.5 mL or 3 mL single patient use prefilled pen per carton in the following presentations: |                                                  |
| Presentation                                                                                                                                                                                                                                                  | Dose Button and Cartridge Holder Color Indicator |
| 60 mg/1.5 mL (40 mg/mL)                                                                                                                                                                                                                                       | Brown                                            |
| 150 mg/1.5 mL (100 mg/mL)                                                                                                                                                                                                                                     | Gold                                             |
| 300 mg/3 mL (100 mg/mL)                                                                                                                                                                                                                                       | (b) (4) white (b) (4)                            |

Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Alhemo. We did not identify any new names that were not previously analyzed; therefore, we did not identify any names that could pose a risk for confusion with Alhemo.

## 2.2.6 COMMUNICATION OF DMEPA'S DETERMINATION

On September 13, 2024, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

## 3 CONCLUSION

The proposed proprietary name, Alhemo, is conditionally acceptable.

### 3.1 COMMENTS TO NOVO NORDISK INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 20, 2024 for BLA 761315 (b) (4) 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.<sup>j</sup>

| *Table 3. 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                                                                                                                                                                                               | <b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>                                                                                                                                                       |
|                                                                                                                                                                                                   | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.                                                                                                   |
| Y/N                                                                                                                                                                                               | <b>Are there inert or inactive ingredients referenced in the proprietary name?</b>                                                                                                                                                                |
|                                                                                                                                                                                                   | 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                                                                                                                                                                                               | <b>Does the proprietary name include combinations of active ingredients?</b>                                                                                                                                                                      |
|                                                                                                                                                                                                   | 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                                                                                                                                                                                               | <b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>                                                                                                                                                                 |
|                                                                                                                                                                                                   | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.                                                                                                                                           |

<sup>j</sup> 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                                                                                                                                    |                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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  $\geq 70\%$ .
- Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
- Low similarity: combined match percentage score  $\leq 54\%$ .

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  $\geq 70$  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.
  - o 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<sup>k</sup>. 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.

- o 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-

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<sup>k</sup> 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 $\geq$ 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><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i> | Y/N                | Do the names have different number of syllables?                                                       |
| Y/N                                                                                                                                                                                                                                                                                       | Are the lengths of the names dissimilar* when scripted?<br><i>*FDA considers the length of names different if the names differ by two or more letters.</i>                              | 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 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$ ). |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1                                                                                                 | <p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Step 2                                                                                                 | <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                                                                                                        | <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> <li>• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</li> <li>• Are the lengths of the names dissimilar* when scripted?</li> <li>• *FDA considers the length of names different if the names differ by two or more letters.</li> <li>• Considering variations in scripting of some letters (such as z and f), is there a different number or</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul> |

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).

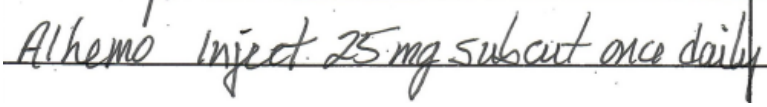
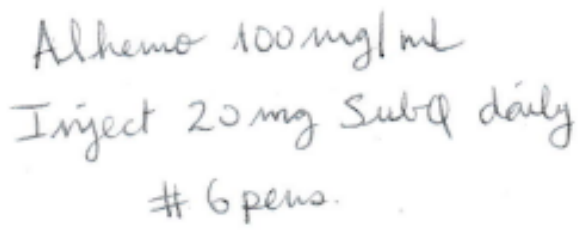
|  |                                                                                                                                                                                                                                                                                                                                                                          |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>placement of upstroke/downstroke letters present in the names?</p> <ul style="list-style-type: none"> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul> |  |
|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 54\%$ ).

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. Alhemo Study (Conducted on 7/16/2024)

| Handwritten Medication Order Prescription                                                                                  | Verbal Prescription                                                                                |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <p><u>Medication Order:</u></p>         | <p>Alhemo<br/>100mg/mL<br/>Inject 20 mg<br/>subcutaneously<br/>daily.<br/>Dispense #6<br/>pens</p> |
| <p><u>Outpatient Prescription:</u></p>  |                                                                                                    |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font)                                                           |                                                                                                    |
| <b>Alhemo</b>                                                                                                              |                                                                                                    |

| FDA Prescription Simulation Responses (Aggregate Report) |           |            |       |      |       |
|----------------------------------------------------------|-----------|------------|-------|------|-------|
| Study Name: Alhemo                                       |           |            |       |      |       |
| People Received Study: 193                               |           |            |       |      |       |
| People Responded: 91                                     |           |            |       |      |       |
| Total                                                    | 26        | 21         | 19    | 25   | 91    |
| INTERPRETATION                                           | INPATIENT | OUTPATIENT | VOICE | CPOE | TOTAL |
| ALHEMO                                                   | 26        | 21         | 4     | 25   | 76    |
| ALHIMO                                                   | 0         | 0          | 1     | 0    | 1     |
| HALHEEMO                                                 | 0         | 0          | 3     | 0    | 3     |
| HALHEMO                                                  | 0         | 0          | 8     | 0    | 8     |
| HALHIMO                                                  | 0         | 0          | 1     | 0    | 1     |
| HAWHEMO                                                  | 0         | 0          | 1     | 0    | 1     |
| HOWHIMO                                                  | 0         | 0          | 1     | 0    | 1     |

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## SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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|                                             |                                                                                                                                  |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| <b>Date of This Review:</b>                 | 8/6/2024                                                                                                                         |
| <b>Responsible OND Division:</b>            | Division of Non-Malignant Hematology (DNH)                                                                                       |
| <b>Application Type and Number:</b>         | BLA 761315                                                                                                                       |
| <b>Product Name and Strength:</b>           | Alhemo (concizumab-mtci) injection<br><div>(b) (4)</div><br>60 mg/1.5 mL (40 mg/mL)<br>150 mg/1.5 mL and 300 mg/3 mL (100 mg/mL) |
| <b>Product Type:</b>                        | Combination Product (Biologic-Device)                                                                                            |
| <b>Applicant/Sponsor Name:</b>              | Novo Nordisk Inc. (Novo)                                                                                                         |
| <b>Nexus NPNS ID #:</b>                     | 2024-258                                                                                                                         |
| <b>DMEPA 2 Biologics Suffix Specialist:</b> | Carlos M Mena-Grillasca, BS Pharm                                                                                                |
| <b>DMEPA 2 Deputy Director:</b>             | Chi-Ming (Alice) Tu, PharmD                                                                                                      |

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## 1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -mtci, for BLA 761315, which was found conditionally acceptable on February 9, 2023<sup>a</sup>, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761315.

### 1.1 Regulatory History

We found the proposed suffix, -mtci, acceptable for BLA 761315 on February 9, 2023<sup>a</sup>. However, BLA 761315 received a Complete Response (CR) letter on April 24, 2023<sup>b</sup>. Thus, Novo submitted a Class 2 Resubmission on June 20, 2024.

## 2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -mtci, using the principles described in the applicable guidance<sup>c</sup>.

We determined that the proposed suffix -mtci, 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 2 ANALYSIS

These findings were shared with OPDP. On August 1, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on August 6, 2024.

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<sup>a</sup> Mena-Grillasca, C. Nonproprietary Name Suffix Review for concizumab-mtci (BLA 761315). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Feb 09. Nexus No.: 2022-122.

<sup>b</sup> Yanoff, L.B. Complete Response (BLA 761315). Silver Spring (MD): FDA, CDER, OND, OCHEN (US); 2023 Apr 24.

<sup>c</sup> Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

## **4 CONCLUSION**

We find the suffix -mtci acceptable and recommend the nonproprietary name concizumab-mtci be used throughout the draft labels and labeling.

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CARLOS M MENA-GRILLASCA  
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CHI-MING TU  
08/06/2024 08:09:58 PM

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**SUFFIX REVIEW FOR NONPROPRIETARY NAME**

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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|                                            |                                                                                                                                  |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| <b>Date of This Review:</b>                | 2/9/2023                                                                                                                         |
| <b>Responsible OND Division:</b>           | Division of Non-Malignant Hematology (DNH)                                                                                       |
| <b>Application Type and Number:</b>        | BLA 761315                                                                                                                       |
| <b>Product Name and Strength:</b>          | Alhemo (concizumab-mtci) injection<br><div>(b) (4)</div><br>60 mg/1.5 mL (40 mg/mL)<br>150 mg/1.5 mL and 300 mg/3 mL (100 mg/mL) |
| <b>Product Type:</b>                       | Combination Product (Biologic-Device)                                                                                            |
| <b>Applicant/Sponsor Name:</b>             | Novo Nordisk Inc. (Novo)                                                                                                         |
| <b>FDA Received Date:</b>                  | August 24, 2022                                                                                                                  |
| <b>Nexus NPNS ID #:</b>                    | 2022-122                                                                                                                         |
| <b>DMAMES Biologics Suffix Specialist:</b> | Carlos M Mena-Grillasca, BS Pharm                                                                                                |
| <b>DMEPA 2 Director:</b>                   | Danielle Harris, PharmD                                                                                                          |

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## 1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Novo for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761315.

## 2 ASSESSMENT OF THE NONPROPRIETARY NAME

On August 24, 2022, Novo submitted a list of 9 suffixes, in their order of preference, to be used in the nonproprietary name of their product<sup>a</sup>. Table 1 presents a list of suffixes submitted by Novo:

| Table 1. Suffixes submitted by Novo*** |         |
|----------------------------------------|---------|
| 1.                                     | mtci    |
| 2.                                     | (b) (4) |
| 3.                                     |         |
| 4.                                     |         |
| 5.                                     |         |
| 6.                                     |         |
| 7.                                     |         |
| 8.                                     |         |
| 9.                                     |         |

We reviewed Novo's proposed suffixes in the order of preference listed by Novo using the principles described in the applicable guidance.<sup>b</sup>

---

<sup>a</sup> Proposed Suffix for Concizumab BLA 761315. Plainsboro (NJ): Novo Nordisk Inc.; 2022 Aug 24. Available from: <\\CDSESUB1\EVSPROD\bla761315\0008\m1\us\proposed-suffix-concizumab.pdf>

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

## **2.1 concizumab-mtci**

Novo's first proposed suffix, -mtci, is comprised of 4 distinct letters. We note that the letters 'mt' in the suffix represents the medical abbreviation for 'micro tablet'. We also note that the suffix -mtci looks similar to the name "Maci", however, Maci is not a drug, but an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full thickness cartilage defects of the knee with or without bone involvement that requires a biopsy of the patient's cartilage cells which are then grown in a laboratory and subsequently implanted into the knee. We considered whether the inclusion of the letters 'mt' within the suffix or the similarity with "Maci" could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -mtci, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products that could be misinterpreted or a cause of medication errors, 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 2 ANALYSIS**

These findings were shared with OPDP. On February 8, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on February 9, 2023.

## **4 CONCLUSION**

We find Novo's proposed suffix -mtci acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to concizumab-mtci. DMEPA 2 will communicate our findings to the Applicant via letter.

### **4.1 Recommendations for Novo Nordisk Inc.**

We find the nonproprietary name, concizumab-mtci, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, concizumab-mtci 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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CARLOS M MENA-GRILLASCA  
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02/14/2023 09:46:07 AM

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## PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

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|                                                                  |                                                                                                                                                 |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date of This Review:</b>                                      | November 18, 2022                                                                                                                               |
| <b>Application Type and Number:</b>                              | BLA 761315                                                                                                                                      |
| <b>Product Name and Strength:</b>                                | Alhemo (concizumab-xxxx) <sup>a</sup> injection, (b) (4)<br>(b) (4) 60 mg/1.5 mL (40 mg/mL), 150 mg/1.5 mL (100 mg/mL), 300 mg/3 mL (100 mg/mL) |
| <b>Product Type:</b>                                             | Combination Product (Biologic-Device)                                                                                                           |
| <b>Rx or OTC:</b>                                                | Prescription (Rx)                                                                                                                               |
| <b>Applicant/Sponsor Name:</b>                                   | Novo Nordisk Inc. (Novo Nordisk)                                                                                                                |
| <b>PNR ID #:</b>                                                 | 2022-1044724720                                                                                                                                 |
| <b>DMEPA 2 Safety Evaluator:</b>                                 | Sue Black, PharmD                                                                                                                               |
| <b>DMEPA 2 Team Leader:</b>                                      | Hina Mehta, PharmD                                                                                                                              |
| <b>DMEPA 2 Associate Director for Nomenclature and Labeling:</b> | Chi-Ming (Alice) Tu, PharmD                                                                                                                     |

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<sup>a</sup> The nonproprietary name suffix for this BLA has not yet been determined; therefore, the placeholder, concizumab-xxxx, is used throughout this review to refer to the nonproprietary name and suffix for this product.

## Contents

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Alhemo, 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. Novo Nordisk submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external name study was previously reviewed under IND 111691 (see Section 1.1 below).

### 1.1 REGULATORY HISTORY

Novo Nordisk previously submitted the proposed proprietary name, Alhemo\*\*\* on June 17, 2019. Subsequently, the proposed name, Alhemo\*\*\*, was found conditionally acceptable on September 19, 2019.<sup>b</sup>

Novo Nordisk submitted the name, Alhemo, for review on August 24, 2022 as part of the marketing application for BLA 761315.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 24, 2022.

- Intended Pronunciation: al-HEE-mo
- Nonproprietary Name: concizumab-xxxx
- Indication of Use: routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with:
  - hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors
  - hemophilia B (congenital factor IX deficiency) with FIX inhibitors
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: (b) (4) 60 mg/1.5 mL (40 mg/mL), 150 mg/1.5 mL (100 mg/mL), 300 mg/3 mL (100 mg/mL)
- Dose and Frequency:
  - Recommended dosing regimen:
    - Day 1: Loading dose of 1 mg/kg
    - Day 2: Once-daily dose of 0.20 mg/kg until individualization of maintenance dose

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<sup>b</sup> Mena-Grillasca, C. Proprietary Name Review for Alhemo (IND 111691). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Sep 16. PNR ID No. 2019-32472570.

- o Individualize maintenance dose once based on the following product plasma concentrations:
  - <200 ng/mL: adjust to a once-daily dose of 0.25 mg/kg
  - 200 to 4000 ng/mL: continue once-daily dose of 0.20 mg/kg
  - >4000 ng/mL: adjust to a once-daily dose of 0.15 mg/kg
- How Supplied: Solution for injection is a clear to slightly opalescent, colorless to slightly yellow liquid, that may contain translucent to white particles (b) (4). Product is available as one 1.5 mL or 3 mL single-patient use prefilled pen per carton in the following presentations:

| Presentation              | Dose Button and Cartridge Holder Color Indicator | NDC Number   |
|---------------------------|--------------------------------------------------|--------------|
| (b) (4)                   |                                                  |              |
| 60 mg/1.5 mL (40 mg/mL)   | brown                                            | 0169-2084-15 |
| 150 mg/1.5 mL (100 mg/mL) | gold                                             | 0169-2080-15 |
| 300 mg/3 mL (100 mg/mL)   | (b) (4)                                          | 0169-2081-03 |

- Storage:
  - o Before use: Store in a refrigerator at 36°F to 46°F (2°C to 8°C) for up to 24 months.
  - o After first use: Store for up to 4 weeks in a refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature below 86°F (30°C).
  - o Store unused product with the cap on and in the original carton to protect from light. Product should not be stored in direct sunlight, and the product pen should be kept away from direct heat. Do not freeze or store it close to a cooling element in a refrigerator. Do not use product if it has been frozen or stored at temperatures above 86°F (30°C).

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Alhemo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Alhemo. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Alhemo.

### 2.2 SAFETY ASSESSMENT

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

### **2.2.1 United States Adopted Names (USAN) Search**

There is no USAN stem present in the proposed proprietary name<sup>c</sup>.

### **2.2.2 Components of the Proposed Proprietary Name**

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

### **2.2.3 Comments from Other Review Disciplines at Initial Review**

On September 26, 2022, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Alhemo at the initial phase of the review.

### **2.2.4 FDA Name Simulation Studies**

Ninety-four (n=94) practitioners participated in DMEPA's prescription studies for Alhemo. The responses did not overlap with any currently marketed products. Appendix B contains the results from the prescription simulation studies.

### **2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results**

Our POCA search<sup>d</sup> identified 31 names with the combined score of  $\geq 55\%$  or individual orthographic or phonetic score of  $\geq 70\%$ . We had identified and evaluated all 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. We note the strength presentations of the proposed product in this submission are (b) (4) 60 mg/1.5 mL (40 mg/mL), 150 mg/1.5 mL (100 mg/mL), and 300 mg/3 mL (100 mg/mL), whereas the strengths previously evaluated were (b) (4) 40 mg/mL, 100 mg/mL under IND 111691. Additionally, we note the dose of the proposed product in this submission is loading dose on first day of 1 mg/kg, followed by once-daily dose on the second day of 0.2 mg/kg until individualization of maintenance dose, where individualization of the maintenance dose may be adjusted to once-daily dose of 0.25 mg/kg, 0.2 mg/kg or 0.15 mg/kg based on product plasma concentrations, whereas the dose previously evaluated was 1 mg/kg once on the first day (loading dose), followed by 0.25 mg/kg once daily (maintenance dose) under IND 111691. All other product characteristics remain the same. We considered these changes during our re-evaluation of the previous names, and we agree with the findings from our previous review for the 30 names evaluated previously. Of the 1 remaining name, we further evaluated it based on the changes in the strength and dose. This name is included in Table 1 below.

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<sup>c</sup> USAN stem search conducted on October 19, 2022.

<sup>d</sup> POCA search conducted on October 19, 2022 in version 5.0.

### **2.2.6 Names Retrieved for Review Organized by Name Pair Similarity**

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

| <b>Table 1. Names Retrieved for Review Organized by Name Pair Similarity</b>                |                        |
|---------------------------------------------------------------------------------------------|------------------------|
| <b>Similarity Category</b>                                                                  | <b>Number of Names</b> |
| Highly similar name pair:<br>combined match percentage score $\geq 70\%$                    | 0                      |
| Moderately similar name pair:<br>combined match percentage score $\geq 55\%$ to $\leq 69\%$ | 1                      |
| Low similarity name pair:<br>combined match percentage score $\leq 54\%$                    | 0                      |

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

Our analysis of the one name in Table 1 determined it will not pose a risk for confusion with Alhemo as described in Appendices C through H.

### **2.2.8 Communication of DMEPA's Determination**

On November 18, 2022, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

## **3 CONCLUSION**

The proposed proprietary name, Alhemo, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at (240) 402-5120.

### **3.1 COMMENTS TO NOVO NORDISK INC.**

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

If any of the proposed product characteristics as stated in your submission, received on August 24, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

### 2. **Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

### **Drugs@FDA**

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther\\_biological](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

### **RxNorm**

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

### **Division of Medication Errors Prevention and Analysis proprietary name consultation requests**

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
  - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2\*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>e</sup>

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<sup>e</sup> National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

**\*Table 2- Prescreening Checklist for Proposed Proprietary Name**

|            |                                                                                                                                                                                                                                                   |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            | Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.                                                 |
| <b>Y/N</b> | <b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>                                                                                                                                                       |
|            | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.                                                                                                   |
| <b>Y/N</b> | <b>Are there inert or inactive ingredients referenced in the proprietary name?</b>                                                                                                                                                                |
|            | 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)). |
| <b>Y/N</b> | <b>Does the proprietary name include combinations of active ingredients?</b>                                                                                                                                                                      |
|            | 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)).                                                                         |
| <b>Y/N</b> | <b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>                                                                                                                                                                 |
|            | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.                                                                                                                                           |
| <b>Y/N</b> | <b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>                                                                                                                               |
|            | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.                                                                                                                          |
| <b>Y/N</b> | <b>Is this a proprietary name of a discontinued product?</b>                                                                                                                                                                                      |
|            | Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.                                                                                   |

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .

- Low similarity: combined match percentage score  $\leq 54\%$ .

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
  - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names<sup>f</sup>. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
  - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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<sup>f</sup> Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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

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

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

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

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

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

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

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

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

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

| <p>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.</p> |                                                                                                                                                                                                    |                           |                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------|
| <u>Orthographic Checklist</u>                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                    | <u>Phonetic Checklist</u> |                                                                                                                  |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>Do the names begin with different first letters?</p> <p><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i></p> | <b>Y/N</b>                | <p>Do the names have different number of syllables?</p>                                                          |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>Are the lengths of the names dissimilar* when scripted?</p> <p><i>*FDA considers the length of names different if the names differ by two or more letters.</i></p>                              | <b>Y/N</b>                | <p>Do the names have different syllabic stresses?</p>                                                            |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>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?</p>                        | <b>Y/N</b>                | <p>Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</p> |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>Is there different number or placement of cross-stroke or dotted letters present in the names?</p>                                                                                              | <b>Y/N</b>                | <p>Across a range of dialects, are the names consistently pronounced differently?</p>                            |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>Do the infixes of the name appear dissimilar when scripted?</p>                                                                                                                                 |                           |                                                                                                                  |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                       | <p>Do the suffixes of the names appear dissimilar when scripted?</p>                                                                                                                               |                           |                                                                                                                  |

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).**

|        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1 | <p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul> |
| Step 2 | <p>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 <b><u>with</u></b> overlapping or similar strengths or doses.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

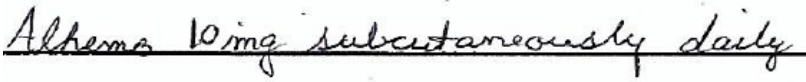
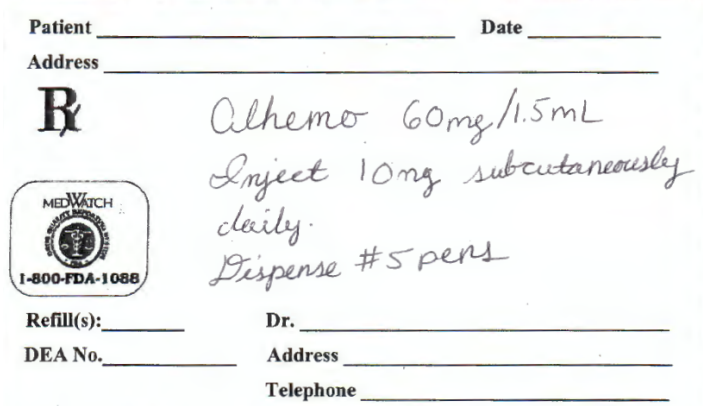
|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul> | <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 54\%$ ).**

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. Alhemo Study (Conducted on September 16, 2022)**

| Handwritten Medication Order/Prescription                                                                                                                                                                                                                                                                                                                                                                                                                            | Verbal Prescription                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p data-bbox="191 394 428 426"><u>Medication Order:</u></p>  <p data-bbox="191 562 496 594"><u>Outpatient Prescription:</u></p>  <p data-bbox="191 1052 1078 1083"><b>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</b></p> <p data-bbox="191 1115 298 1146"><b>Alhemo</b></p> | <p data-bbox="1157 394 1263 426">Alhemo</p> <p data-bbox="1157 447 1357 594">60 mg/1.5 mL<br/>Inject 10 mg<br/>subcutaneously<br/>daily</p> <p data-bbox="1157 611 1317 684">Dispense #5<br/>pens</p> |

# **FDA Prescription Simulation Responses (Aggregate Report)**

|                       |                  |             |              |                   |                                                  |
|-----------------------|------------------|-------------|--------------|-------------------|--------------------------------------------------|
| Study Name: Alhemo    |                  |             |              |                   | 264 People Received Study<br>94 People Responded |
| <b>Total</b>          | <b>25</b>        | <b>26</b>   | <b>17</b>    | <b>26</b>         |                                                  |
| <b>INTERPRETATION</b> | <b>INPATIENT</b> | <b>CPOE</b> | <b>VOICE</b> | <b>OUTPATIENT</b> | <b>TOTAL</b>                                     |
| ALFEMO                | 0                | 0           | 1            | 0                 | 1                                                |
| ALHEEMO               | 0                | 0           | 1            | 0                 | 1                                                |
| ALHEM                 | 1                | 0           | 0            | 0                 | 1                                                |
| ALHEMA                | 1                | 0           | 0            | 0                 | 1                                                |
| ALHEMEO               | 0                | 0           | 1            | 0                 | 1                                                |
| ALHEMO                | 17               | 26          | 13           | 25                | 81                                               |
| ALHEMO 60MG/1.5ML     | 0                | 0           | 0            | 1                 | 1                                                |
| ALHEMS                | 1                | 0           | 0            | 0                 | 1                                                |
| ALHEMZ                | 5                | 0           | 0            | 0                 | 5                                                |
| ALHIMO                | 0                | 0           | 1            | 0                 | 1                                                |

**Appendix C:** Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ ) – N/A

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is  $\geq 55\%$  to  $\leq 69\%$ ) with no overlap or numerical similarity in Strength and/or Dose – N/A

**Appendix E:** Moderately Similar Names (e.g., combined POCA score is  $\geq 55\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose – N/A

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 54\%$ ) – N/A

**Appendix G:** Names not likely to be confused or not used in usual practice settings for the reasons described.

| No. | Name   | POCA Score (%) | Failure preventions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----|--------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | Alsuma | 60             | <p>Per Drugs@FDA, NDA 022377 Alsuma (sumatriptan succinate) injection, 6 mg/0.5 mL, from Meridian Medcl is discontinued with no generic equivalents available (no TE code per Drugs@FDA). NDA 022377 withdrawn FR effective July 21, 2017.</p> <p>Per RedBook, Alsuma (sumatriptan succinate) injection, 6 mg/0.5 mL, from Pfizer Labs is deactivated (last AWP price history was in 2015) with no Orange Book code.</p> <p>Per Google, Meridian became a part of Pfizer in 2011. Alsuma appears to be an auto-injector.</p> <p>Alsuma is not found in DailyMed, and Facts &amp; Comparisons.</p> |

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion<sup>§</sup>. – N/A

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<sup>§</sup> 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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