# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761299Orig1s000

# PROPRIETARY NAME REVIEW(S)

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

## Memorandum

**From:**

Carlos M Mena-Grillasca, BS Pharm
Biologics Suffix Specialist, DMAMES/OMEPRM/OSE

**Through:**

Mishale Mistry, PharmD, MPH
Director, Division of Medication Error Prevention and Analysis I/OMEPRM/OSE

**Subject:** Re-assessment of the nonproprietary name for BLA 761299

**Regulatory History:**

Alvotech USA Inc. submitted two Biologics License Applications (BLA 761205 and BLA 761299) pursuant to Section 351(k) of the Public Health Service Act. BLA 761205 is a proposed biosimilar to US-licensed Humira, whereas BLA 761299 is a proposed interchangeable to US-licensed Humira.

- BLA 761205 was initially submitted on September 4, 2020.
- DMEPA found the proposed suffix -ryvk conditionally acceptable for BLA 761205 on May 25, 2021[a].
- BLA 761205 received a Complete Response letter on August 11, 2022[b].

[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 May 25. Nexus NPNS ID No.: 2020-29.

[b] Targum, S.L. Complete Response (BLA 761205). Silver Spring (MD): FDA, CDER, OND, OII, DDD (US); 2022 Aug 11.

- BLA 761205 was resubmitted as a Class 2 Resubmission on October 13, 2022.
- DMEPA 1 found the proposed suffix -ryvk conditionally acceptable upon re-review[a].
- BLA 761205 received a Complete Response letter on April 12, 2023[b].
- BLA 761299 was initially submitted on December 20, 2021.
- DMEPA 1 found that the new BLA 761299 can be managed under the same suffix,-ryvk, as BLA 761205[c].
- BLA 761299 received a Complete Response letter on December 20, 2022[d].
- BLA 761299 was resubmitted as a Class 2 Resubmission on December 28, 2022.
- DMEPA 1 maintained the previous determination that BLA 761299 can be managed under the same suffix, -ryvk, as BLA 761205[e].
- BLA 761299 received a Complete Response letter on June 28, 2023[f].
- BLA 761299 was resubmitted as a Class 2 Resubmission on August 24, 2023.

Re-assessement:

We maintain our previous determination that a different nonproprietary name for BLA 761299 would not be designated in this particular case. Thus, BLA 761299 can be managed under the same nonproprietary name, adalimumab-ryvk, as BLA 761205.

[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Mar 02. Nexus NPNS ID No.: 2022-152.

[b] Targum, S.L. Complete Response (BLA 761205). Silver Spring (MD): FDA, CDER, OND, OII, DDD (US); 2023 Apr 12.

[c] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761299). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Nov 15. Nexus NPNS ID No.: 2021-66.

[d] Nikolov, N.P. Complete Response (BLA 761299). Silver Spring (MD): FDA, CDER, OND, OII, DRTM (US); 2022 Dec 20.

[e] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761299). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Mar 31.

[f] Nikolov, N.P. Complete Response (BLA 761299). Silver Spring (MD): FDA, CDER, OND, OII, DRTM (US); 2023 Jun 28.

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CARLOS M MENA-GRILLASCA
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**PROPRIETARY NAME MEMORANDUM**

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

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

| | |
|---|---|
| **Date of This Review:** | October 30, 2023 |
| **Application Type and Number:** | BLA 761299 |
| **Product Name and Strength:** | Simlandi<br>adalimumab-ryvk<br>injection<br>40 mg/0.4 ml |
| **Product Type:** | Combination Product (Biologic-Device) |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Alvotech USA Inc. (Alvotech) |
| **PNR ID #:** | 2023-1044725311 |
| **DMEPA 1 Safety Evaluator:** | Lissa C. Owens, PharmD |
| **DMEPA 1 Team Leader:** | Idalia E. Rychlik, PharmD |
| **DMEPA 1 Director:** | Mishale Mistry, PharmD, MPH |

# 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Simlandi, which was found conditionally acceptable under BLA 761299 on March 20, 2023.[a] However, the application received a complete response (CR) on June 8, 2023.

Thus, Alvotech submitted the name, Simlandi, under BLA 761299 for re-review on August 24, 2023. We note that there are two additional proposed indications (Hidradenitis Suppurativa and Uveitis) for BLA 761299. We note that the dose for Uveitis is the same as the dose for Plaque Psoriasis and the dose for Hidradenitis Suppurativa follows the other proposed indications and does not require the need for a new dose or strength. All other product characteristics remain the same.

# 2 METHODS AND DISCUSSION

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Simlandi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Simlandi. The Division of Rheumatology and Transplant Medicine (DRTM) did not comment on the findings of OPDP's assessment for Simlandi.

## 2.2 SAFETY ASSESSMENT

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

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The October 4, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Simlandi.

## 2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On October 30, 2023, we communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

# 3 CONCLUSION

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

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[a] Owens, L. Proprietary Name Review for Simlandi (BLA 761299). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 MAR 20. PNR ID No. 2022-1044724915

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

### 3.1 COMMENTS TO ALVOTECH USA INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 24, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCE


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

   USAN Stems List contains all the recognized USAN stems.

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MISHALE P MISTRY
11/02/2023 10:32:32 AM

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

## Memorandum

**From:**

Carlos M Mena-Grillasca, BS Pharm
Biologics Suffix Specialist, DMAMES/OMEPRM/OSE

**Through:**

Mishale Mistry, PharmD, MPH
Director, Division of Medication Error Prevention and Analysis I/OMEPRM/OSE

**Subject:** Re-assessment of the nonproprietary name for BLA 761299

**Regulatory History:**

Alvotech USA Inc. submitted two Biologics License Applications (BLA 761205 and BLA 761299) pursuant to Section 351(k) of the Public Health Service Act. BLA 761205 is a proposed biosimilar to US-licensed Humira, whereas BLA 761299 is a proposed interchangeable to US-licensed Humira.

- BLA 761205 was initially submitted on September 4, 2020.
- DMEPA found the proposed suffix -ryvk conditionally acceptable for BLA 761205 on May 25, 2021[a].

[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 May 25. Nexus NPNS ID No.: 2020-29.

- BLA 761205 received a Complete Response letter on August 11, 2022[a].
- BLA 761205 was resubmitted as a Class 2 Resubmission on October 13, 2022.
- DMEPA 1 found the proposed suffix -ryvk conditionally acceptable upon re-review[b].
- BLA 761299 was initially submitted on December 20, 2021.
- DMEPA 1 found that the new BLA 761299 can be managed under the same suffix,-ryvk, as BLA 761205[c].
- BLA 761299 received a Complete Response letter on December 20, 2022[d].
- BLA 761299 was resubmitted as a Class 2 Resubmission on December 28, 2022.

Re-assessement:

We maintain our previous determination that a different nonproprietary name for BLA 761299 would not be designated in this particular case. Thus, BLA 761299 can be managed under the same nonproprietary name, adalimumab-ryvk, as BLA 761205.

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[a] Targum, S.L. Complete Response (BLA 761205). Silver Spring (MD): FDA, CDER, OND, OII, DDD (US); 2022 Aug 11.

[b] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Mar 02. Nexus NPNS ID No.: 2022-152.

[c] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for adalimumab-ryvk (BLA 761299). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Nov 15. Nexus NPNS ID No.: 2021-66.

[d] Nikolov, N.P. Complete Response (BLA 761299). Silver Spring (MD): FDA, CDER, OND, OII, DRTM (US); 2022 Dec 20.

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MISHALE P MISTRY
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**PROPRIETARY NAME REVIEW**

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

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

| | |
|---|---|
| **Date of This Review:** | March 20, 2023 |
| **Application Type and Number:** | BLA 761299 |
| **Product Name and Strength:** | Simlandi (adalimumab-ryvk) Injection, 40 mg/0.4 mL |
| **Product Type:** | Combination Product (Drug-Biologic) |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Alvotech USA Inc. (Alvotech) |
| **PNR ID #:** | 2022-1044724915 |
| **DMEPA 1 Safety Evaluator:** | Lissa C. Owens, PharmD |
| **DMEPA 1 Team Leader:** | Idalia E. Rychlik, PharmD |
| **DMEPA 1 Director:** | Mishale Mistry, PharmD, MPH |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Simlandi, 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. Alvotech submitted an external name study, conducted (b) (4) for this proposed proprietary name that we previously reviewed[a].

## 1.1 REGULATORY HISTORY

Alvotech previously submitted the proposed proprietary name, Simlandi under BLA 761205 on September 4, 2020, to the Division of Dermatology and Dentistry (DDD). We found the name, Simlandi*** conditionally acceptable under BLA 761205 on December 2, 2020.[b] However, BLA 761205 received a Complete Response (CR) on August 11, 2022. Alvotech responded to the CR and re-submitted the name, Simlandi, for review on October 13, 2022, and we found the name conditionally acceptable under BLA 761205 on December 14, 2022.[c] This BLA is pending approval.

On December 20, 2021, Alvotech submitted the proposed proprietary name, Simlandi under BLA 761299 as an interchangeable biosimilar to Humira (BLA 125-57) to the Division of Rheumatology and Transplant Medicine (DRTM). We found the name, Simlandi conditionally acceptable under BLA 761299 on March 8, 2022.[d] However, BLA 761299 received a Complete Response (CR) on December 20, 2022.

Thus, Alvotech responded to the CR and re-submitted the name Simlandi for review under BLA 761299 on December 28, 2022. We note that our previous reviews under DDD and DRTM included the same indications and product characteristics as currently proposed.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 28, 2022.

- Intended Pronunciation: sim lan' dee
- Nonproprietary Name: adalimumab-ryvk

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[a] Owens, L. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461

[b] Owens, L. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461.

[c] Patel, M. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 DEC 14. PNR ID No. 2022-1044724809

[d] Owens, L. Proprietary Name Review for Simlandi (BLA 761299). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 MAR 08. PNR ID No. 2021-1044724348

- Indication of Use: Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Crohn's Disease (CD), Ulcerative Colitis (UC), Plaque Psoriasis (Ps)
- Route of Administration: subcutaneous
- Dosage Form: Injection
- Strength: 40 mg/0.4 mL
- Dose and Frequency:

**Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis (2.1):**

- *Adults*: 40 mg every other week.
- Some patients with RA not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.

**Juvenile Idiopathic Arthritis (2.2):**

| Pediatric Weight 2 Years of Age and older | Recommended Dosage |
|---|---|
| 30 kg (66 lbs) and greater | 40 mg every other week |

**Crohn's Disease (2.3):**

- *Adults:* 160 mg on Day 1 (given in one day or split over two consecutive days); 80 mg on Day 15; and 40 mg every other week starting on Day 29.
- *Pediatric Patients 6 Years of Age and Older:*

| Pediatric Weight | Recommended Dosage | |
|---|---|---|
| | Days 1 and 15 | Starting on Day 29 |
| 40 kg (88 lbs) and greater | Day 1: 160 mg (single dose or split over two consecutive days)<br>Day 15: 80 mg | 40 mg every other week |

**Ulcerative Colitis (2.4):**

- *Adults*: 160 mg on Day 1 (given in one day or split over two consecutive days); 80 mg on Day 15 and 40 mg every other week starting on Day 29 Discontinue in patients without evidence of clinical remission by eight weeks (Day 57).

**Plaque Psoriasis (2.5):**

- *Adults*: 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

- How Supplied: a carton containing one or two alcohol preps and one or two dose packs. Each pack consists of a single-dose pen, containing a 1 mL prefilled glass syringe with a fixed 29-gauge (½ inch) needle, providing 40 mg/0.4 mL
- Storage: Must be refrigerated at 36°F to 46°F (2°C to 8°C). DO NOT FREEZE
- Reference Listed Drug/Reference Product: proposed biosimilar interchangeable to US-licensed Humira (adalimumab) BLA 125057

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Simlandi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Simlandi. The Division of Rheumatology and Transplant Medicine (DRTM) concurred with the findings of OPDP's assessment for Simlandi.

## 2.2 SAFETY ASSESSMENT

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

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

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

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

Alvotech did not provide a derivation or intended meaning for the proposed proprietary name, Simlandi, in their submission. This proprietary name is comprised of a single word. We note that Simlandi contains the letter strings: '-im-' an abbreviation for the route of administration 'intramuscular administration', '-la-' an abbreviation used for 'long acting' (i.e. a long acting dosage form), and '-ml-' an abbreviation for 'milliliters' a unit of measure. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that due to the location of these abbreviations in the middle of the name and their lack of prominence, it is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we conclude that in this case, the letter strings '-im-', '-la-', '-ml-' and in the name are acceptable.

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

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

On February 6, 2023, the Division of Rheumatology and Transplant Medicine (DRTM) did not forward any comments or concerns relating to Simlandi at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

Ninety (n=90) practitioners participated in DMEPA's prescription studies for Simlandi. One respondent in the Computerized Physician Order Entry (CPOE) study selected Abciximab instead of Simlandi from the picklist. Upon further evaluation, we note that the participant took 17 seconds to respond to the sample of Simlandi and typed 'abc' instead of 'sim', and as a result their picklist did not include Simlandi. Thus, they selected Abciximab from the picklist.

[e] USAN stem search conducted on January 13, 2023.

We further evaluated the name pair and note that the FDA's Phonetic and Orthographic Computer Analysis (POCA) program[f] calculates a combined score of 36%, suggesting there is low similarity between these names. As such, we find the risk of name confusion minimal and evaluate this name pair in Appendix F.

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

Our POCA search[g] identified 128 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We identified and evaluated all of the names in our previous proprietary name reviews[h,i,j]. 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 that none of the product characteristics have changed, and we agree with the findings from our past reviews for the names evaluated previously.

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

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

**Table 1. Names Retrieved for Review Organized by Name Pair Similarity**

| Similarity Category | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 0 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 1 |

[f] POCA search conducted on March 20, 2023 in version 5.2.

[g] POCA search conducted on January 13, 2023 in version 5.1.

[h] Owens, L Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461

[i] Owens, L Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 MAR 08. PNR ID No. 2021-1044724348

[j] Patel, M Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 DEC 22. PNR ID No. 2022-1044724809

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

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

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

On March 20, 2023, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

## 3 CONCLUSION

The proposed proprietary name, Simlandi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

### 3.1 COMMENTS TO ALVOTECH USA INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 28, 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).

***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. [k]

[k] 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. |
|---|---|
| **Y/N** | **Is the proposed name obviously similar in spelling and pronunciation to other names?** |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| **Y/N** | **Are there inert or inactive ingredients referenced in the proprietary name?** |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| **Y/N** | **Does the proprietary name include combinations of active ingredients?** |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| **Y/N** | **Is there a United States Adopted Name (USAN) stem in the proprietary name?** |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |
| **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, 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[1]. 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

[1] 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 ≥ 70%).**

| Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose. | | | |
|---|---|---|---|
| Orthographic Checklist | | Phonetic Checklist | |
| **Y/N** | Do the names begin with different first letters?<br>*Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.* | **Y/N** | Do the names have different number of syllables? |
| **Y/N** | Are the lengths of the names dissimilar* when scripted?<br>**FDA considers the length of names different if the names differ by two or more letters.* | **Y/N** | Do the names have different syllabic stresses? |
| **Y/N** | Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? | **Y/N** | Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? |
| **Y/N** | Is there different number or placement of cross-stroke or dotted letters present in the names? | **Y/N** | Across a range of dialects, are the names consistently pronounced differently? |
| **Y/N** | Do the infixes of the name appear dissimilar when scripted? | | |
| **Y/N** | Do the suffixes of the names appear dissimilar when scripted? | | |

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

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

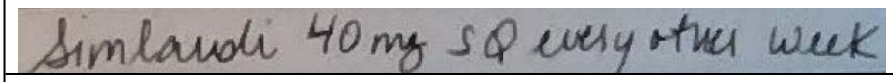
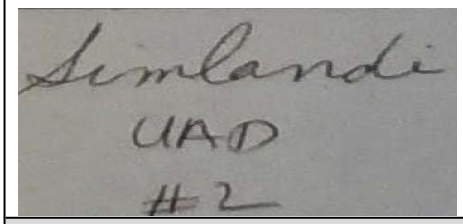
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when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

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

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

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

**Figure 1. Simlandi Study (Conducted on January 20, 2023)**

| **Handwritten Medication Order/Prescription** | **Verbal Prescription** |
|---|---|
| Medication Order:<br>  <br> | Simlandi<br>UAD<br>#2 |
| Outpatient Prescription:<br>  <br> | |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| **Simlandi** | |

**Study Name: Simlandi**
As of Date 2/3/2023

258 People Received Study
90 People Responded

Study Name: Simlandi

| **Total** | **21** | **22** | **20** | **27** | |
|---|---|---|---|---|---|
| **INTERPRETATION** | **INPATIENT** | **CPOE** | **VOICE** | **OUTPATIENT** | **TOTAL** |
| ABCIXIMAB | 0 | 1 | 0 | 0 | 1 |
| SIIMLANDI | 0 | 0 | 0 | 1 | 1 |
| SIMLAND | 0 | 0 | 0 | 1 | 1 |
| SIMLANDI | 4 | 21 | 10 | 25 | 60 |
| SIMLANDY | 0 | 0 | 2 | 0 | 2 |
| SIMLARDI | 1 | 0 | 0 | 0 | 1 |
| SIMLAUDI | 13 | 0 | 0 | 0 | 13 |
| SIMLAUDLI | 1 | 0 | 0 | 0 | 1 |
| SIMLAVOLI | 2 | 0 | 0 | 0 | 2 |
| SYMLANDEE | 0 | 0 | 1 | 0 | 1 |
| SYMLANDI | 0 | 0 | 6 | 0 | 6 |
| SYMLANDY | 0 | 0 | 1 | 0 | 1 |

**Appendix C:** Highly Similar Names (e.g., combined POCA score is ≥70%) - N/A

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

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

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Abciximab | 36 |

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

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion[m]. - N/A

[m] 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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LISSA C PRINGLE-OWENS
03/20/2023 03:53:38 PM

IDALIA E RYCHLIK
03/20/2023 03:56:18 PM

MISHALE P MISTRY
03/20/2023 04:17:12 PM

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

Memorandum

From:

Carlos M Mena-Grillasca, BS Pharm
Biologics Suffix Specialist, DMAMES
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Carlos Mena-grillasca -S
Digitally signed by Carlos Mena-grillasca -S
Date: 2022.11.07 13:18:40 -05'00'

Through:

Irene Z Chan, PharmD, BCPS
Director, Division of Medication Error Prevention and Analysis I
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Irene Z. Chan -S
Digitally signed by Irene Z. Chan -S
Date: 2022.11.09 13:47:51 -05'00'

Gerald Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Gerald J. Dal Pan -S
Digitally signed by Gerald J. Dal Pan -S
Date: 2022.11.09 18:10:56 -05'00'

**Subject:** Evaluation of the nonproprietary name for BLA 761299

Alvotech USA Inc. (Alvotech) submitted two Biologics License Applications (BLA 761205 and BLA 761299) pursuant to Section 351(k) of the Public Health Service Act. BLA 761205 is a proposed biosimilar to US-licensed Humira (hereafter referred to as "Humira"), whereas BLA 761299 is a proposed interchangeable with Humira. Under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim[a]. If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original

[a] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

application. BLA 761205 for Simlandi (adalimumab-xxxx) was submitted on September 4, 2020 to the Division of Dermatology and Dentistry and received a Complete Response (CR) letter on August 11, 2022 due to facilities inspection observations. On October 13, 2022, Alvotech resubmitted BLA 761205 in response to the CR letter and the PDUFA goal date to take action on the application is April 12, 2023. BLA 761299 for Simlandi (adalimumab-xxxx), which is the subject of this memorandum, was subsequently submitted on December 20, 2021, to the Division of Rheumatology and Transplant Medicine and the PDUFA goal date to take action on the application is December 20, 2022 (standard review) because an original application was not yet approved.

Per Alvotech, BLA 761299 for interchangeability includes the content submitted to BLA 761205 for biosimilarity, with the following additions/revisions: addition of data to support interchangeability, update of CMC and clinical summary modules with responses provided to information requests received for BLA 761205, incorporation of final CSR into Module 2 for completeness, and Module 3 updated to include two new drug substance batch release methods as well as a change in testing site for the autoinjector functional testing. Furthermore, (b) (4) based on new data.

The drug substance in BLA 761299 is the same as the drug substance in BLA 761205, and both BLAs propose a liquid formulation[a] in single-dose prefilled autoinjector with a 40 mg/0.4 mL strength.

The proposed product is a tumor necrosis factor blocker. Both BLAs propose the same indications and formulation, in the same dosage form, strength, dose, route and frequency of administration. The only difference between the BLAs is that the proposed product under BLA 761205 is seeking biosimilarity to Humira while the proposed product under BLA 761299 is seeking interchangeabilty with Humira. Alvotech is proposing separate U.S. prescribing information (USPI) but proposing the same proprietary name, Simlandi, for both BLAs.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, stating the Agency's intention to designate proper names that include four-letter distinguishing suffixes for biological products[b]. Both of these 351(k) applications are within the scope of this naming guidance.

As such, the proposed nonproprietary name suffix -ryvk was found conditionally acceptable[c] for BLA 761205. We carefully considered whether the nonproprietary name for BLA 761299 should include a different distinguishing suffix than that designated for BLA 761205 or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating the same proper name (i.e., adalimumab-ryvk) for BLA 761299. Among the factors we have considered are the following:

[a] The official USP recognized dosage form for the proposed formulation is *Injection*.
[b] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "naming guidance").
[c] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761205. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 May 25. Nexus NPNS ID. 2020-29.

1. We note that all product characteristics (e.g. indications, formulation, dosage form, strength, dose, route, and frequency of administration) are identical for BLA 761205 and BLA 761299. The only difference between the two BLAs is that the proposed product under BLA 761205 is seeking biosimilarity to Humira while the proposed product under BLA 761299 is seeking interchangeability with Humira.

2. The drug substance in BLA 761205 is the same as the drug substance in BLA 761299, and both BLAs propose a liquid formulation[a] in single-dose prefilled autoinjector with a 40 mg/0.4 mL strength.

3. We note above that under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim[a]. If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original application. Thus, Alvotech submitted two separate BLAs. Had BLA 761205 been approved prior to submission of BLA 761299, the addition of interchangeability could be managed under a supplement to BLA 761205, which would not have resulted in a change to the proper name under the approach to nonproprietary naming described in the final guidance.

4. Alvotech is proposing to have a separate USPI for each BLA and the same proprietary name. The naming convention of using the same proprietary name for biosimilar and interchangeable products is generally found acceptable. We have not identified any safety or misbranding concerns that would render the proprietary name, Simlandi, unacceptable for BLA 761299.

5. As noted in the final Nonproprietary Naming of Biological Products guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a manufacturing lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. As noted above, the indications, formulation, dosage form, strength, route of administration, and frequency of administration for both BLAs are same— i.e., they differ only with respect to seeking biosimilarity to Humira vs. seeking interchangeability with Humira. Also, as noted above, Alvotech is the applicant for BLA 761205 and BLA 761299.

Given the above factors, a different nonproprietary name for BLA 761299 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761299 could create confusion and would not further the goals of the naming convention.

[a] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving the same nonproprietary name for BLA 761299[a]. We based this determination upon consideration of all the factors outlined above. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name for this BLA.

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

## Comments for Alvotech for BLA 761299:

We have determined that adalimumab-ryvk will be the proper name designated in the license should your 351(k) BLA be approved during this review cycle.

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

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/s/

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CARLOS M MENA-GRILLASCA
11/10/2022 12:20:45 PM

IRENE Z CHAN
11/15/2022 09:11:17 AM

**PROPRIETARY NAME REVIEW**

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

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

| | |
|---|---|
| **Date of This Review:** | March 8, 2022 |
| **Application Type and Number:** | BLA 761299 |
| **Product Name and Strength:** | Simlandi (adalimumab-xxxx[a]) Injection, 40 mg/0.4 mL |
| **Total Product Strength:** | 40 mg/0.4 mL per single-dose pen |
| **Product Type:** | Combination Product (Drug-Biologic) |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Alvotech USA, Inc. (Alvotech) |
| **PNR ID #:** | 2021-1044724348 |
| **DMEPA 1 Safety Evaluator:** | Lissa C. Owens, PharmD |
| **DMEPA 1 Team Leader:** | Idalia E. Rychlik, PharmD |

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "adalimumab-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Simlandi, 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. Alvotech submitted an external name study, conducted (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761205 (see section 1.1 below).

## 1.1 REGULATORY HISTORY

Alvotech previously submitted the proposed proprietary name, Simlandi*** on September 4, 2020, to the Division of Dermatology and Dentistry (DDD). We found the name, Simlandi*** acceptable under BLA 761205 on December 2, 2020.[b] BLA 761205 is pending approval.

On December 20, 2021, Alvotech submitted BLA 761299 to the Division of Rheumatology and Transplant Medicine (DRTM). Under that BLA, Alvotech submitted the name Simlandi for review. We note that our previous review under DDD included the same indications and product characteristics as currently proposed for Division of Rheumatology and Transplant Medicine (DRTM).

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 20, 2021.

- Intended Pronunciation: sim lan' dee
- Nonproprietary Name: adalimumab-xxxx
- Indication of Use: Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn’s Disease, Ulcerative Colitis, Plaque Psoriasis
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 40 mg/0.4 mL
- Dose and Frequency:

[b] Owens, L. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461.

**Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis (2.1):**

- *Adults*: 40 mg every other week.
- Some patients with RA not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week.

**Juvenile Idiopathic Arthritis (2.2):**

| Pediatric Weight 2 Years of Age and older | Recommended Dosage |
|---|---|
| 30 kg (66 lbs) and greater | 40 mg every other week |

**Crohn's Disease (2.3):**

- *Adults:* 160 mg on Day 1 (given in one day or split over two consecutive days); 80 mg on Day 15; and 40 mg every other week starting on Day 29.
- *Pediatric Patients 6 Years of Age and Older:*

| Pediatric Weight | Recommended Dosage | |
|---|---|---|
| | Days 1 and 15 | Starting on Day 29 |
| 40 kg (88 lbs) and greater | Day 1: 160 mg (single dose or split over two consecutive days)<br>Day 15: 80 mg | 40 mg every other week |

**Ulcerative Colitis (2.4):**

- *Adults*: 160 mg on Day 1 (given in one day or split over two consecutive days); 80 mg on Day 15 and 40 mg every other week starting on Day 29 Discontinue in patients without evidence of clinical remission by eight weeks (Day 57).

**Plaque Psoriasis (2.5):**

- *Adults*: 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

- How Supplied: a carton containing one or two alcohol preps and one or two dose packs. Each pack consists of a single-dose pen, containing a 1 mL prefilled glass syringe with a fixed 29-gauge (½ inch) needle, providing 40 mg/0.4 mL
- Storage: Must be refrigerated at 36°F to 46°F (2°C to 8°C). DO NOT FREEZE
- Reference Product: Humira (BLA 125057)

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Simlandi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Rheumatology and Transplant Medicine (DRTM) concurred with the findings of OPDP's assessment for Simlandi.

### 2.2 SAFETY ASSESSMENT

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

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

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

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

Alvotech did not provide a derivation or intended meaning for the proposed proprietary name, Simlandi, 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 are misleading or can contribute to medication error.

We note that Simlandi contains the letter string '-im-', an abbreviation for the route of administration 'intramuscular administration.' We maintain the acceptability of the letter string in this case and discussed the rationale in our previous review[d].

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

On January 19, 2022, the Division of Rheumatology and Transplant Medicine (DRTM) did not forward any comments or concerns relating to Simlandi at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

One hundred and five (n=105) practitioners participated in DMEPA's prescription studies for Simlandi. 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[e] identified 122 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review[f]. 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 that none of the product characteristics have changed, and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two names not previously analyzed. These names are included in Table 1 below.

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

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

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[c] USAN stem search conducted on January 27, 2022.

[d] Owens, L. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461

[e] POCA search conducted on January 27, 2022 in version 4.4.

[f] Owens, L. Proprietary Name Review for Simlandi (BLA 761205). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 02. PNR ID No. 2020-42615461

| Table 1. Names Retrieved for Review Organized by Name Pair Similarity | |
|---|---|
| **Similarity Category** | **Number of Names** |
| Highly similar name pair:<br>combined match percentage score ≥70% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 2 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 0 |

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

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

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

On March 8, 2022, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

## 3 CONCLUSION

The proposed proprietary name, Simlandi, is acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

### 3.1 COMMENTS TO ALVOTECH USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 20, 2021, 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).

***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. [g]

[g] 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. |
|---|---|
| **Y/N** | **Is the proposed name obviously similar in spelling and pronunciation to other names?** |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| **Y/N** | **Are there inert or inactive ingredients referenced in the proprietary name?** |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| **Y/N** | **Does the proprietary name include combinations of active ingredients?** |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| **Y/N** | **Is there a United States Adopted Name (USAN) stem in the proprietary name?** |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |
| **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, 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[h]. 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

[h] 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

| Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose. | | | |
|---|---|---|---|
| Orthographic Checklist | | Phonetic Checklist | |
| **Y/N** | Do the names begin with different first letters?<br>*Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.* | **Y/N** | Do the names have different number of syllables? |
| **Y/N** | Are the lengths of the names dissimilar* when scripted?<br>**FDA considers the length of names different if the names differ by two or more letters.* | **Y/N** | Do the names have different syllabic stresses? |
| **Y/N** | Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? | **Y/N** | Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? |
| **Y/N** | Is there different number or placement of cross-stroke or dotted letters present in the names? | **Y/N** | Across a range of dialects, are the names consistently pronounced differently? |
| **Y/N** | Do the infixes of the name appear dissimilar when scripted? | | |
| **Y/N** | Do the suffixes of the names appear dissimilar when scripted? | | |

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

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

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

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

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

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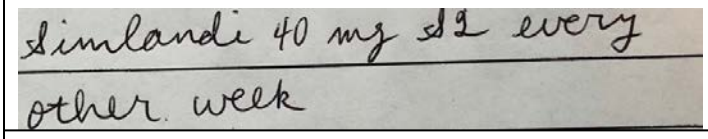
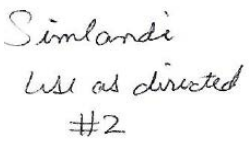
**Appendix B: Prescription Simulation Samples and Results**

**Figure 1. Simlandi Study (Conducted on January 21, 2022)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Simlandi<br>UAD<br>#2 |
| Outpatient Prescription:<br>  <br> | |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| Simlandi | |

**Study Name: Simlandi**
As of Date 3/1/2022

261 People Received Study
105 People Responded

Study Name: Simlandi

| Total | 33 | 24 | 23 | 25 | |
|---|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **CPOE** | **VOICE** | **INPATIENT** | **TOTAL** |
| SIMLAND | 1 | 0 | 0 | 0 | 1 |
| SIMLANDE | 0 | 0 | 1 | 0 | 1 |
| SIMLANDI | 32 | 24 | 10 | 25 | 91 |
| SIMLANDIE | 0 | 0 | 1 | 0 | 1 |
| SIMLANDY | 0 | 0 | 6 | 0 | 6 |
| SYMLAMVI | 0 | 0 | 1 | 0 | 1 |
| SYMLANDI | 0 | 0 | 2 | 0 | 2 |
| SYMLANDY | 0 | 0 | 1 | 0 | 1 |
| SYMLANDYE | 0 | 0 | 1 | 0 | 1 |

**Appendix C:** Highly Similar Names (e.g., combined POCA score is ≥70%)-N/A

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

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

| No. | **Proposed name:** Simlandi<br>**Established name:** adalimumab-xxxx<br>**Dosage form:** Injection<br>**Strength(s):** 40 mg/0.4 mL<br>**Usual Dose:** 40 mg every other week or 40 mg every week or 80 mg every other week or 80 mg Day 1 then 40 mg every other week or 160 mg split over two days, then 80 mg on Day 15 and 40 mg every other week starting on Day 29 | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | Omlonti*** | 61 | This name pair has sufficient orthographic and phonetic differences. |
| 2. | Asciminib | 60 | This name pair has sufficient orthographic and phonetic differences |

**Appendix F:** Low Similarity Names (e.g., combined POCA score is ≤54%)-N/A

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

**Appendix H:** Names not likely to be confused due to absence of attributes that are known to cause name confusion[i].-N/A

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

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

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/s/

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LISSA C OWENS
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03/08/2022 04:27:10 PM