

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761343Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

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

Date of This Review:	2/16/2024
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761343
Product Name and Strength:	Selarsdi (ustekinumab-aekn) injection 45 mg/0.5 mL and 90 mg/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Alvotech USA Inc. (Alvotech)
Nexus NPNS ID #:	2023-210
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -aekn, for BLA 761343, which was found conditionally acceptable on July 27, 2023^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761343.

1.1 Regulatory History

FDA found the proposed suffix, -aekn, acceptable for BLA 761343 on July 27, 2023^a. However, BLA 761343 received a Complete Response (CR) letter on October 11, 2023^b. Thus, Alvotech submitted a Class 2 Resubmission on October 16, 2023.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -aekn, using the principles described in the applicable guidance^c.

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

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On January 31, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on February 16, 2024.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for Selarsdi (ustekinumab-aekn) (BLA 761343). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Jul 27. Nexus NPNS ID No.: 2022-131.

^b Targum, S.L. Complete Response (BLA 761343). Silver Spring (MD): FDA, CDER, OND, DDD (US); 2023 Oct 11.

^c 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 -aekn acceptable and recommend the nonproprietary name ustekinumab-aekn be used throughout the draft labels and labeling.

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

/s/

CARLOS M MENA-GRILLASCA
02/16/2024 11:11:02 AM

MISHALE P MISTRY
02/16/2024 11:20:49 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)

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Date of This Review:	December 27, 2023
Application Type and Number:	BLA 761343
Product Name and Strength:	Selarsdi (ustekinumab-aekn) injection, 45 mg/0.5 mL and 90 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Alvotech USA Inc. (Alvotech)
PNR ID #:	2023-1044725443
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Selarsdi, 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. An external name study, conducted by [REDACTED] ^{(b) (4)} for this proposed proprietary name, was previously reviewed under BLA 761343 (see section 1.1).

1.1 REGULATORY HISTORY

Alvotech previously submitted the proposed proprietary name, Selarsdi, under BLA 761343, on October 11, 2022. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Selarsdi, conditionally acceptable.^a However, The Division of Dermatology and Dentistry (DDD) issued a Complete Response (CR) for the application on October 11, 2023. Alvotech resubmitted the application along with a request for review of the proposed proprietary name Selarsdi on October 16, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 16, 2023.

- Intended Pronunciation: seh-LARS-dee
- Nonproprietary Name: ustekinumab-aekn
- Indication of Use:
 - Adult patients with:
 - moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy
 - active psoriatic arthritis (PsA)
 - Pediatric patients 6 years and older with:
 - moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
 - active psoriatic arthritis (PsA)
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 45 mg/0.5 mL and 90 mg/mL
- Dose and Frequency: 45 mg or 90 mg initially and 4 weeks later followed by 45 mg or 90 mg every 12 weeks

^a Fanari, M. Proprietary Name Review for Selarsdi (BLA 751343). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 Dec 14. PNR ID No. 2022-1044724798.

- How Supplied: Individually packaged, single-dose prefilled syringes (45 mg/0.5 mL and 90 mg/mL). Each prefilled syringe is equipped with a 29 gauge fixed ½ inch needle equipped with a passive safety device and a needle cover. Not made with natural rubber latex.
- Storage: must be refrigerated at 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. If needed, individual prefilled syringes may be stored at room temperature up to 30°C (86°F) for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage. Do not use after the expiration date on the carton or on the prefilled syringe.
- Selarsdi (ustekinumab-aekn) is a proposed biosimilar to US-licensed Reference Product, Stelara (ustekinumab) BLA 125261.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 *Components of the Proposed Proprietary Name*

Alvotect did not provide a derivation or intended meaning for the proposed proprietary name, Selarsdi, in their submission. This proprietary name is comprised of a single word that has the abbreviations of 'long-acting' (i.e. 'LA') and 'long acting release' (LAR), in the name. In this case, we find that the placement and presentation of the 'la' and 'lar' letter strings are included in such a manner that they lack prominence, are unlikely to be misconstrued as medical abbreviations, and thus would not be expected to pose a risk for medication errors. Thus, we

^b USAN stem search conducted on November 7, 2023.

conclude that the abbreviations ‘la’ and ‘lar’ in the name are acceptable. There were no additional components of the name that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On November 29, 2023, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Selarsdi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Sixty-seven (67) practitioners participated in DMEPA’s prescription studies for Selarsdi. One participant’s computerized physician order entry (CPOE) response overlapped with a currently marketed product, SelRx, and one participant in the verbal prescription study misinterpreted Selarsdi as ‘Stelardi’, which is similar to the Reference Product, Stelara. Stelara was identified in the newly conducted POCA search for this review (see section 2.2.5).

We further evaluated these names below.

Selarsdi vs. SelRx

One participant identified SelRx in the CPOE study. It appears that this participant entered an incorrect sequence of letters, ‘Selr’ instead of ‘Sela’, when searching for the study name. As a result, the CPOE generated a pick list that did not contain Selarsdi as a choice, and the participant proceeded to incorrectly select SelRx as their response. It appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study, and the study response is unlikely to be representative of a plausible CPOE-based risk. Nonetheless, we evaluated the name pair, Selarsdi and SelRx. SelRx (selenium sulfide) is a topical antifungal shampoo indicated for the treatment of dandruff and seborrheic dermatitis. This name pair is moderately similar (combined POCA score of 62%) with no overlap or numerical similarity in strength and/or dose. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized (see Appendix D).

Selarsdi vs. Stelara

One participant in the verbal prescription study misinterpreted Selarsdi as ‘Stelardi’. We note that the response ‘Stelardi’ looks and sounds similar to the US-licensed Reference Product, Stelara. We considered the differences in the phonetic and orthographic characteristics of this name pair and determined the risk for a medication error between this name pair is adequately minimized (see Appendix E).

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^c identified 117 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated a majority of the

^c POCA search conducted on November 7, 2023 in version 5.3.

names in our previous proprietary name review.^d 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 FDA Prescription Simulation Study and POCA search that required evaluation. 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: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	4
Low similarity name pair: 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 4 names contained in Table 1 determined none of the names will pose a risk for confusion with Selarsdi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On December 27, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Selarsdi, is conditionally acceptable.

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

3.1 COMMENTS TO ALVOTECH USA INC.

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

^d Fanari, M. Proprietary Name Review for Selarsdi (BLA 751343). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 Dec 14. PNR ID No. 2022-1044724798.

If any of the proposed product characteristics as stated in your submission, received on October 16, 2023, 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.^e

^e 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, Cerner RxNorm, 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 ≥ 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^f. 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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

- c. FDA Prescription Simulation Studies: DMEPA staff 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) 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 $\geq 70\%$).

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.

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <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? <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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

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

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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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. Selarsdi Study (Conducted on November 13, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Selarsdi Administer 45 mg subcutaneously once</i>	Selarsdi 45 mg/0.5 mL Bring to clinic Dispense #1
<u>Outpatient Prescription:</u> <i>Selarsdi 45 mg/0.5 mL</i> <i>Bring to clinic</i> <i>#1</i>	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Selarsdi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Selarsdi People Received Study: 229 People Responded: 67					
Total	16	20	12	19	67
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
SALARZDI	0	0	1	0	1
SALERZDI	0	0	1	0	1
SELABSDI	0	1	0	0	1
SELARDI	0	1	0	0	1
SELARODI	0	7	0	0	7
SELARSDI	12	6	0	18	36
SELARSOLI	4	0	0	0	4
SELARZDI	0	0	2	0	2
SELARZDY	0	0	1	0	1
SELRX	0	0	0	1	1
SELURODI	0	2	0	0	2
SELURSDI	0	3	0	0	3
SILARSTY	0	0	1	0	1
SOLARSDY	0	0	2	0	2
SOLARZDI	0	0	2	0	2
STELARDI	0	0	1	0	1
SYLARZDY	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

No.	Name	POCA Score (%)
1.	SelRx	62
2.	(b) (4)***	60
3.	Claradin	58

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

No.	Proposed name: Selarsdi Established name: ustekinumab-aekn Dosage form: injection Strength(s): 45 mg/0.5 mL and 90 mg/mL Usual Dose: 45 mg or 90 mg initially and 4 weeks later, followed by 45 mg or 90 mg every 12 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Stelara	62	Orthographically, the upstroke letter in the 2 nd position of Stelara and the upstroke letter in the 7 th position of Selarsdi provide some orthographic differences between the names. Phonetically, the last syllables (dee <i>versus</i> ah) provide some phonetic differences. We note that Stelara is the US-licensed Reference Product for Selarsdi.

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. – N/A

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^g. – N/A

^g 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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AMY J BAO
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YEVGENIYA M KOGAN
12/27/2023 02:48:50 PM

MISHALE P MISTRY
12/28/2023 10:32:31 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

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

Date of This Review:	7/27/2023
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761343
Product Name and Strength:	Selarsdi (ustekinumab-aekn) injection 45 mg/0.5 mL or 90 mg/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Alvotech USA Inc. (Alvotech)
FDA Received Date:	October 11, 2022
Nexus NPNS ID #:	2022-131
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Acting Director:	Irene Z. Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Alvotech for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761343.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 11, 2022, Alvotech submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Alvotech also provided findings from their own internal study^b, evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Alvotech:

Table 1. Suffixes submitted by Alvotech***	
1.	ae kn
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

^a FDA-Designated Suffixes for Review BLA 761343. Arlington (VA): Alvotech USA Inc.; 2022 Oct 11. Available from: [\\CDSESUB1\EVSPROD\bla761343\0001\m1\us\118-prop-names\1-18-suffixes-proposals.pdf](#)

^b Appendix – Proposed Suffixes Analysis. Arlington (VA): Alvotech USA Inc.; 2022 Oct 11. Available from: [\\CDSESUB1\EVSPROD\bla761343\0001\m1\us\118-prop-names\1-18-appendix-proposed-suffix-analysis.pdf](#)

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

2.1 ustekinumab-aekn

Alvotech's first proposed suffix, -aekn, is comprised of 4 distinct letters.

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

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On July 26, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on July 27, 2023.

4 CONCLUSION

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

4.1 Recommendations for Alvotech USA Inc.

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

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

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CARLOS M MENA-GRILLASCA
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IRENE Z CHAN
07/27/2023 06:38:59 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 14, 2022
Application Type and Number:	BLA 761343
Product Name and Strength:	Selarsdi (ustekinumab-xxxx) ^a injection, 45 mg/0.5 mL and 90 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Alvotech (Alvotech)
PNR ID #:	2022-1044724798
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Selarsdi, 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 by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 11, 2022.

- Intended Pronunciation: seh-LARS-dee
- Nonproprietary Name: ustekinumab-xxxx
- Indication of Use:

Adult patients with:

- moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy.
- active psoriatic arthritis (PsA)

Pediatric patients 6 years and older with:

- moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- active psoriatic arthritis (PsA)
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 45 mg/0.5 mL and 90 mg/mL
- Dose and Frequency: 45 mg or 90 mg initially and 4 weeks later followed by 45 mg or 90 mg every 12 weeks
- How Supplied: Individually packaged single dose prefilled syringes. Each prefilled syringe is equipped with a 29 gauge fixed ½ inch needle equipped with a passive safety device and a needle cover.
- Storage: must be refrigerated at 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. If needed, individual prefilled syringes may be stored at room temperature up to 30°C (86°F) for a maximum single period of up to 30 days in the original carton to protect from light. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator.
- Reference Listed Drug/Reference Product: Stelara (BLA 125261)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 Components of the Proposed Proprietary Name

Alvotech did not provide a derivation or intended meaning for the proposed proprietary name, Selarsdi, in their submission. This proprietary name is comprised of a single word that has the abbreviations of 'long-acting' (i.e. 'LA') and 'long acting release' (LAR), in the name. In this case, we find that the placement and presentation of the 'la' and 'lar' letter strings are included in such a manner that they lack prominence, are unlikely to be misconstrued as medical abbreviations, and thus would not be expected to pose a risk for medication errors. Thus, we conclude that the abbreviations 'la' and 'lar' in the name are acceptable. There were no additional components of the name that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

The Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Selarsdi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-eight (88) practitioners participated in DMEPA's prescription studies for Selarsdi. 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.

^b USAN stem search conducted on October 13, 2022.

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

Our POCA search^c identified 118 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

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

Table 1 lists the names retrieved from our POCA search and (b) (4) external 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: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	104
Low similarity name pair: combined match percentage score $\leq 54\%$	15

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

Our analysis of the 120 names contained in Table 1 determined none of the names will pose a risk for confusion with Selarsdi as described in Appendices C through H.

2.2.8 *of DMEPA's Determination*

On December 14, 2022, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Selarsdi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO ALVOTECH

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

^c POCA search conducted on October 13, 2022 in version 5.0.

If any of the proposed product characteristics as stated in your submission, received on October 11, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.^d

^d 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 $\geq 70\%$.
 - 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 ≥ 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^e. 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

^e 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 $\geq 70\%$).

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <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? <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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

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

	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. - Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? - Is there different number or placement of cross-stroke or dotted letters present in the names? - Do the infixes of the name appear dissimilar when scripted? - Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) - Do the names have different number of syllables? - Do the names have different syllabic stresses? - Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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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. Selarsdi Study (Conducted on October 28, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Selarsdi 90mg subcutaneously once</i>	Selarsdi 45 mg/0.5 mL Bring to clinic
<u>Outpatient Prescription:</u> <i>Selarsdi</i> <i>45mg/0.5mL</i> <i>Bring to clinic</i>	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Selarsdi	

FDA Prescription Simulation Responses (Aggregate Report)

263 People Received Study

88 People Responded

Study Name: Selarsdi

Total	21	21	22	24	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
CHILARSDI	0	0	1	0	1
SCHILARZDY	0	0	1	0	1
SELARSDI	18	21	0	23	62
SELARSOLI	0	0	0	1	1
SELASDI	1	0	0	0	1
SELASSDI	1	0	0	0	1
SELORSDI	1	0	0	0	1
SHEILARZDI	0	0	1	0	1
SHELARSDI	0	0	2	0	2
SHELARSDIE	0	0	1	0	1
SHELARSDY	0	0	3	0	3
SHELARZDEE	0	0	2	0	2
SHELARZDI	0	0	5	0	5
SHELARZEEE	0	0	1	0	1
SHILARSDI	0	0	1	0	1
SHILARSDY	0	0	1	0	1
SHILARZDI	0	0	2	0	2
UNKNOWN	0	0	1	0	1

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

No.	Proposed name: Selarsdi Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL and 90 mg/mL Usual Dose: 45 mg or 90 mg initially and 4 weeks later followed by 45 mg or 90 mg every 12 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Selarsdi	100	Name subject of this review.

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

No.	Name	POCA Score (%)
1.	Silafed	65
2.	Simlandi***	64
3.	Allres D	62
4.	Selrx	62
5.	Clearskin	62
6.	Netarsudil	61
7.	Siladryl Das	60
8.	Elastin	60
9.	Relax-Ds	60
10.	Ceclor Cd	60
11.	Mellaril-S	60
12.	Striverdi	59
13.	Serostim	59
14.	Soliris	59
15.	Solesta	59
16.	Shellcap Pd	58
17.	Siladryl	58
18.	Solaraze	58
19.	Sovaldi	58
20.	Elbasvir	58
21.	Idelalisib	58
22.	Solaraze	58
23.	Siltuss Das	57
24.	Clearasil	57
25.	Relagard	57
26.	Remular-S	57

No.	Name	POCA Score (%)
27.	Solarcaine	56
28.	Claris	56
29.	Selseb	56
30.	Skelaxin	56
31.	Silvera	56
32.	Setlakin	56
33.	Clariscan	55
34.	Silymarin	55
35.	(b) (4)***	55
36.	Silace	55
37.	Pylarify	55
38.	Sildec Pe	55

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

No.	Proposed name: Selarsdi Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL and 90 mg/mL Usual Dose: 45 mg or 90 mg initially and 4 weeks later followed by 45 mg or 90 mg every 12 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Evrysdi	62	This name pair has sufficient orthographic and phonetic differences.
3.	Stelara	62	This name pair has sufficient orthographic and phonetic differences.
4.	Synercid	60	This name pair has sufficient orthographic and phonetic differences.
5.	Ilaris	56	This name pair has sufficient orthographic and phonetic differences.
6.	Eligard 7.5	56	This name pair has sufficient orthographic and phonetic differences.
7.	Eligard 45	56	This name pair has sufficient orthographic and phonetic differences.
8.	Eligard 30	56	This name pair has sufficient orthographic and phonetic differences.
9.	Eligard 22.5	56	This name pair has sufficient orthographic and phonetic differences.
10.	Eligard	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Selarsdi Established name: ustekinumab-xxxx Dosage form: injection Strength(s): 45 mg/0.5 mL and 90 mg/mL Usual Dose: 45 mg or 90 mg initially and 4 weeks later followed by 45 mg or 90 mg every 12 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
11.	Solurex LA	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Dilcardia Sr	54
2.	Elaprase	53
3.	Delavirdine	53
4.	Relagesic	53
5.	Dermasil	52
6.	Risperdal	52
7.	Sclareolide	50
8.	Parsely Seed Oil	50
9.	Seysara	50
10.	Sandril	48
11.	Sildenafil	48
12.	Serpasil-Esidrix #1	47
13.	Serpasil-Esidrix #2	47
14.	Salvia Sclarea Seed Oil	45
15.	Ibsrela	42

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.	Celadrin	62	International product formally marketed in Malaysia and Canada.
2.	(b) (4)***	62	Proposed proprietary name for NDA 211340 found unacceptable by DMEPA (2018-27739069 dated 2/27/2018). Product approved under the proprietary name Katerzia.

No.	Name	POCA Score (%)	Failure preventions
3.	Solvadi	62	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
4.	Asellacrin 2	60	Brand discontinued with no generic equivalent available. NDA 017726 was withdrawn FR effective 11/12/2002.
5.	Asellacrin 10	60	Brand discontinued with no generic equivalent available. NDA 017726 was withdrawn FR effective 11/12/2002.
6.	(b) (4)***	60	Proposed proprietary name withdrawn by the Applicant on 10/2/2019. Product approved under the proprietary name Upneeq (NDA 212520).
7.	Serpasil	59	Discontinued product with no available generics. NDA 9115 and 9434 withdrawn FR effective 09/04/1996. Bulk powder formulation is available as a veterinary product.
8.	Saralasin	59	Name identified in Rx Norm. Established name for NDA 18009 (Sarenin) withdrawn FR effective 9/29/1995. No generic equivalents are available.
9.	Siladyl	59	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
10.	Laverdia	59	Veterinary product.
11.	(b) (4)***	59	Proposed proprietary name for IND 124813 found unacceptable by DMEPA (2020-43195603 dated 12/21/2020). Product approved under the proprietary name Auvelity (NDA 215430).
12.	Seldane-D	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Siladyl Sa	58	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
14.	Klaricid Iv	57	International product marketed in numerous international countries.
15.	Solostar	57	Name is a modifier associated with several insulin products (Apridra, Insulin Glargine and Lantus).
16.	Tilarin	56	International product marketed in Italy.
17.	Delatest	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
18.	Solensia	56	Veterinary Product.
19.	Indolar Sr	56	International product marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
20.	Salsalte	56	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
21.	Selank	56	Veterinary Product (Bulk powder for animal drug compounding).
22.	Parsidol	56	Discontinued product with no available generics. NDA 9078 withdrawn FR effective 09/29/1995.
23.	(b) (4)***	56	Proposed proprietary name for IND 123554 found unacceptable by DMEPA (2020-38040942 dated 5/13/2020). Product approved under the proprietary name Cibingo (NDA 213871).

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^f.

No.	Name	POCA Score (%)
1.	Daliresp	64
2.	Klerist-D	62
3.	Celery Seed Oil	61
4.	Theolair-Sr	59
5.	Allerx-D	58
6.	Tenar Pse	58
7.	Tiliroside	58
8.	Xolremdi***	58
9.	Allerest	57
10.	Allres Pd	57
11.	Alavert D	56
12.	Allerfed	56
13.	Allerhist-D	56
14.	Allersol A	56
15.	Balversa	56
16.	Bellaspas	56
17.	Cervidil	56
18.	Clorfed Ii	56
19.	Della Soft	56
20.	Dermarest	56
21.	Felypressin	56
22.	Ferrous Ds	56

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

No.	Name	POCA Score (%)
23.	Filspari***	56
24.	Full Marks	56
25.	Paser D/R	56
26.	Trelstar	56
27.	Verard	56
28.	Allerphed	55
29.	(b) (4)***	55
30.	Filgrastim	55
31.	Folgard	55
32.	Valertest	55
33.	Versed	55

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MELINA N FANARI
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MADHURI R PATEL
12/14/2022 07:36:05 PM

MISHALE P MISTRY
12/14/2022 08:33:02 PM