CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761123Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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:	November 3, 2020
Application Type and Number:	BLA 761123
Product Name and Strength:	Saphnelo (anifrolumab) Injection, 300 mg/2 mL (150 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AstraZeneca Pharmaceuticals LP (AstraZeneca)
Panorama #:	2020-41991579
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Idalia Rychlik, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Saphnelo, 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. AstraZeneca submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

AstraZeneca previously submitted the proposed proprietary name (b) (4) *** on January 19, 2019. However, we found the name, (b) (4) *** unacceptable (b) (4) under IND 101849 on July 11, 2019.[a]

Thus, AstraZeneca submitted the name, Saphnelo, for review on August 10, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 10, 2020.

- Intended Pronunciation: saf ne'loe
- Nonproprietary Name: anifrolumab
- Indication of Use: Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE) (b) (4)
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 300 mg/2 mL (150 mg/mL)
- Dose and Frequency: 300 mg every four weeks
- How Supplied: (b) (4)
- Storage: 2 mL of concentrate in a (b) (4) clear (b) (4) glass vial closed by a (b) (4) elastomeric stopper sealed with an aluminum overseal.

[a] McMillan, T.. Proprietary Name Review for (b) (4) (IND 101849). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jul 19. Panorama No. 2019-28736904.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

AstraZeneca did not provide a derivation or intended meaning for the proposed proprietary name, Saphnelo, 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.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 1, 2020 e-mail, the Division of Rheumatology and Transplant Medicine (DRTM) did not forward any comments or concerns relating to Saphnelo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-four practitioners participated in DMEPA's prescription studies for Saphnelo. 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[c] identified 88 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

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[b] USAN stem search conducted on August 12, 2020.

[c] POCA search conducted on August 12, 2020 in version 4.3.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) (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 ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	68
Low similarity name pair: combined match percentage score ≤54%	19

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

Our analysis of the 88names contained in Table 1 determined none of the names will pose a risk for confusion with Saphnelo as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) via e-mail on October 28, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Rheumatology and Transplant Medicine (DRTM) on November 3, 2020, they stated no additional concerns with the proposed proprietary name, Saphnelo.

3 CONCLUSION

The proposed proprietary name, Saphnelo, 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 ASTRAZENECA PHARMACEUTICALS LP

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

If any of the proposed product characteristics as stated in your submission, received on August 10, 2020, 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. [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 ≥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[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. 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? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 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. 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 **with** 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?

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

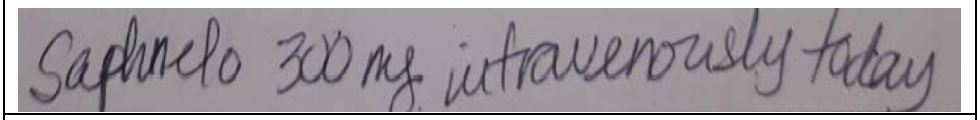
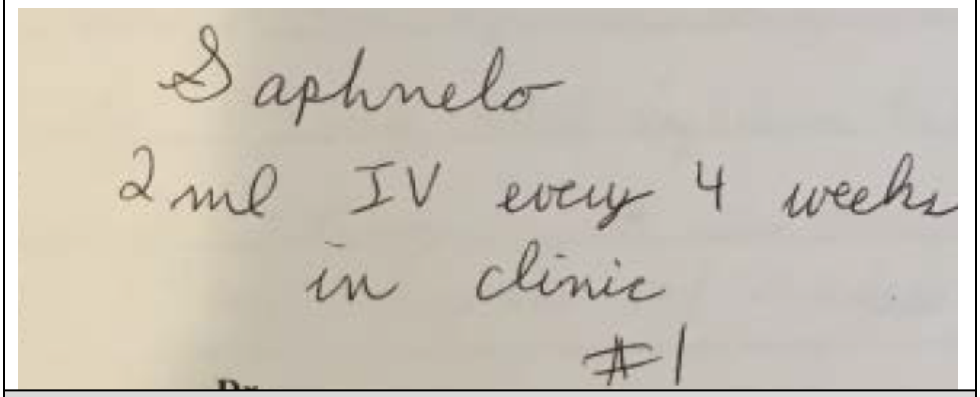
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity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

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Saphnelo Study (Conducted on August 28, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Saphnelo	Saphnelo 2 mL IV every 4 weeks in clinic #1

FDA Prescription Simulation Responses (Aggregate Report)

208 People Received Study
84 People Responded

Study Name: Saphnelo

Total	25	17	24	18	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
SAFNALO	0	0	1	0	1
SAFNELLO	0	0	4	0	4
SAFNELO	0	0	1	0	1
SAPHMELO	1	0	0	0	1
SAPHNELO	24	17	0	16	57
SAPLINELO	0	0	0	1	1
SPHNELO	0	0	0	1	1
STAPHMELO	0	0	2	0	2
TAFMELO	0	0	1	0	1
TAFNELLO	0	0	2	0	2
TAFNELO	0	0	6	0	6
TAFTNELLO	0	0	1	0	1
TASMELLO	0	0	2	0	2
TASMELO	0	0	1	0	1
TASNELO	0	0	1	0	1
TAZNELLO	0	0	1	0	1
ZAFNELLO	0	0	1	0	1

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

No.	**Proposed name:** Saphnelo **Established name:** anifrolumab **Dosage form:** Injection **Strength(s):** 300 mg/2 mL (150 mg/mL) **Usual Dose:** 300 mg every four weeks	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Saphnelo	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Savella	62
2.	Xermelo	56

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

No.	**Proposed name:** Saphnelo **Established name:** anifrolumab **Dosage form:** Injection **Strength(s):** 300 mg/2 mL (150 mg/mL) **Usual Dose:** 300 mg every four 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.	Spasdel	68 Phon-74	This name pair has sufficient orthographic and phonetic differences.
2.	Haponal	63 Ortho-70	This name pair has sufficient orthographic and phonetic differences.
3.	Phenol	62 Ortho-71	This name pair has sufficient orthographic and phonetic differences.
4.	Sleepinal	60	This name pair has sufficient orthographic and phonetic differences.
5.	Tusnel C	60	This name pair has sufficient orthographic and phonetic differences.
6.	Seasonale	60	This name pair has sufficient orthographic and phonetic differences.
7.	Bisphenol A	60 Ortho-72	This name pair has sufficient orthographic and phonetic differences.
8.	Pamelor	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Saphnelo **Established name:** anifrolumab **Dosage form:** Injection **Strength(s):** 300 mg/2 mL (150 mg/mL) **Usual Dose:** 300 mg every four 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**
9.	Sotalol	58	This name pair has sufficient orthographic and phonetic differences.
10.	Senna Plus	58	This name pair has sufficient orthographic and phonetic differences.
11.	1-Naphthol	57	This name pair has sufficient orthographic and phonetic differences.
12.	Spasmolin	56	This name pair has sufficient orthographic and phonetic differences.
13.	Sebulon	56	This name pair has sufficient orthographic and phonetic differences.
14.	Sernivo	55	This name pair has sufficient orthographic and phonetic differences.
15.	Santyl	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Osphena	54 73-ortho
2.	Pscn5a-Neo	54 72-ortho
3.	Saphris	52
4.	Sal-Plant Gel	51 71-ortho
5.	Cefzil	50 Phon-71
6.	Palpeon	50 Ortho-70
7.	Phospha 250 Neutral	50 Ortho-70
8.	Anthelios 20	49 Ortho-71
9.	Anthelios 40	49 Ortho 71

No.	Name	POCA Score (%)
10.	Healon	48 Ortho-71
11.	Healon5	48 Ortho-71
12.	Alphanate	47 Ortho-71
13.	Alphanine	46 Ortho-71
14.	Serophene	46 Otho-71
15.	Alophen	44 Ortho-73
16.	Alpha-Asarone	44 Ortho-72
17.	Salonpas Pain Gel	43 Ortho-70
18.	Alphen	42 Ortho-71
19.	Alpha Ionone	40 Ortho-71

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.	Sano Log	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4) ***	66	Proposed proprietary name (b) (4) under IND 101849 was found unacceptable (OSE #2019-28736904 dated July 11, 2019. The proposed proprietary name Saphnelo was submitted on August 10, 2020 under the pending BLA 761123 and is the subject of this review.
3.	Soni-Slo	62	International product marketed in Ireland.
4.	Sno Pilo	60	International product marketed in Ireland.
5.	Phenobel	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
6.	Silanol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Spasmonal	58	International product marketed in Thailand.
8.	Sevoflo	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Salamol	57	International product marketed in the United Kingdom.
10.	Cefenil	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Staphcillin	56	Brand discontinued with no generic equivalents available. NDA 050117 and ANDA 061449 are withdrawn FR effective 9/29/1995 and10/10/2000 respectively.
12.	Suphera	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Sandalore	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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.	De-Sone La	65
2.	Phenazo	65
3.	Tessalon	62
4.	Zena-Lo	62
5.	Tavneos	61
6.	Phenol Ez	60
7.	Ponstel	60
8.	Phoslo	60
9.	Tepanil	60
10.	Tussanil	59

[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 (%)
11.	Diphenyl	59
12.	Phos Cal	59
13.	Pandel	59
14.	Ephynal	59
15.	Cophene No. 2	59
16.	Pasmol	59
17.	Desonil	58
18.	Patanol	58
19.	Rosanil	58
20.	Panthenol	58
21.	Pathilon	58
22.	Buphenyl	57
23.	Phosveda	56
24.	Farnesol	56
25.	Caplenal	56
26.	Panlor	56
27.	Ephensin-La	56
28.	Phenolax	56
29.	Phenolate	56
30.	Cinalog	56
31.	Esmolol	55
32.	Zonalon	55
33.	Lusonal	55
34.	Ethanol	55
35.	Phenflu	55
36.	K-Phos No 2	55
37.	Phosphasal	55
38.	Phenasep	55

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/s/

TERESA S MCMILLAN
11/03/2020 02:31:09 PM

IDALIA E RYCHLIK
11/03/2020 03:49:02 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

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 20, 2020
Responsible OND Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761123
Product Name and Strength:	Saphnelo[a] (anifrolumab-fnia) injection 300 mg/2 mL (150 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	AstraZeneca AB (AstraZeneca)
FDA Received Date:	July 31, 2020
OSE RCM #:	2020-1714
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

[a] Proposed proprietary name currently under review.

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by AstraZeneca for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761123.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On July 31, 2020, AstraZeneca submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by AstraZeneca:

Table 1. Suffixes submitted by AstraZeneca***

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

[a] Request for Review of Suffixes for Proper Name BLA 761163. Södertälje (Sweden): AstraZeneca AB; 2020 Jul 31. Available from: \\CDSESUB1\evsprod\bla761123\0001\m1\us\request-for-review-of-suffixes-for-proper-name.pdf

We reviewed AstraZeneca's proposed suffixes in the order of preference listed by AstraZeneca, using the principles described in the applicable guidance.[a]

2.1 anifrolumab-fnia

AstraZeneca's first proposed suffix, -fnia, is comprised of four distinct letters. We note that the letters 'ia' in the suffix represent the medical abbreviation for 'intra articular', 'intra arterial', and 'intra amniotic'. We considered whether the inclusion of the letters 'ia' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -fnia, 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'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated October 20, 2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) via e-mail on October 20, 2020.

4 CONCLUSION

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

4.1 Recommendations for AstraZeneca AB

We find the nonproprietary name, anifrolumab-fnia, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, anifrolumab-fnia will be the proper name designated in the license. You should revise your proposed labels and labeling

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[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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 would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
10/20/2020 05:17:08 PM

DANIELLE M HARRIS
10/21/2020 02:52:21 PM