CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761032Orig1s000

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:	February 26, 2016
Application Type and Number:	BLA 761032
Product Name and Strength:	Siliq (brodalumab) Injection 210 mg/1.5 mL Pre-filled syringe
Product Type:	Single Ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	AstraZeneca
Panorama #:	2015-2328008
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Acting Team Leader:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Siliq, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this product with the BLA.

1.1 REGULATORY HISTORY

DMEPA previously reviewed the proposed name, Siliq, during the IND phase and found the name acceptable[1]. We note that the product characteristics have changed since our proprietary name review. During the IND phase, the Sponsor was evaluating three strengths (105 mg, 140 mg, and 210 mg); however, they are proposing only the 210 mg strength in the NDA.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 23, 2015 proprietary name submission:

- Intended Pronunciation: sil' eek
- Active Ingredient: Brodalumab
- Indication of Use: Treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 210 mg/1.5 mL Pre-filled syringe
- Dose and Frequency: 210 mg by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks.
- How Supplied: 2 pre-filled syringes per carton
- Storage: Refrigerated 36°F to 46°F (2°C to 8°C)
- Container and Closure Systems: n/a

[1] Mena-Grillasca C. Proprietary Name Review for Siliq (IND 104671). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 May 07. OSE RCM No.: 2014-45186.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Dermatology and Dental Products (DDDP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Siliq, 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 FDA Name Simulation Studies

Sixty-four practitioners participated in DMEPA's prescription studies. One participant in the voice study misinterpreted the study name Siliq as Salic; Salic-2 is an over-the-counter salicylic acid gel product for the treatment of acne. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 7, 2016 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

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[1]USAN stem search conducted on February 9, 2016.

[2] POCA search conducted on January 5, 2016.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	70
Low similarity name pair: combined match percentage score ≤49%	0

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Siliq, will be available in a 210 mg strength. Since this is not a typical strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Siliq that were not identified in POCA, and found to have an overlap in strength with Siliq.

The PR°PLLR™ search did not identify any names of concern.

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

Our analysis of the 73 names contained in Table 1 determined none of the names will pose a risk for confusion 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 Dermatology and Dental Products (DDDP) via e-mail on February 22, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on February 26, 2016, they stated no additional concerns with the proposed proprietary name, Siliq.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 23, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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 DNCE. OPDP or DNCE 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 DNCE 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. [1]

***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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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)).

[1] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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.

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

   Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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 ≥50% 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:

<table>
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o 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.
o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
o Similar sounding doses: 15 mg is similar in sound to 50 mg

</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>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?

</td><td>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?

</td></tr>
</table>

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Siliq Study (Conducted on January 22, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Siliq Inject 210mg subcutaneously today Outpatient Prescription: Siliq Inject 210 mg subcutaneously every 2 weeks Disp: 1 box Dr. OSE	Siliq Inject 210 mg subcutaneously every 2 weeks Disp. 1 box

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 2/9/2016

239 People Received Study

64 People Responded

Total	24	21	19
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**
SALEEK	0	1	0
SALIC	0	1	0
SALICQ	0	1	0
SALIQUE	0	1	0
SELEEK	0	2	0
SELEK	0	1	0
SELIQ	0	5	0
SELIQUE	0	3	0
SELLIXE	0	1	0
SIBLIQ	0	0	1
SILIC	0	1	0
SILIG	6	0	0
SILIG INJECT	0	0	1
SILIQ	18	0	13
SILIQ 210 MG	0	0	1
SILIQ INJECT	0	0	3
SILIQUE	0	1	0
SULIQUE	0	1	0
SYLIC	0	1	0
ZOLEEK ??	0	1	0

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

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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.	Siliq	100	Proposed name subject of this review.
2.	Salic-2	78	Orthographic: The suffixes of this name pair have sufficient orthographic differences. Other: • Dose: 210 mg vs. Apply to the affected area or UAD • Although Salic-2 is listed in the Dailymed database; it is not listed in any other major drug database (i.e. Drugs@FDA, Facts and Comparisons, Clinical Pharmacology, Micromedex Red Book, CVS, Walgreens, and Riteaid). In addition, Salic-2 is not even available for purchase at its manufacturer website (Sohm). Instead, the manufacturer sells the product under the name "Fohm". Therefore, based on the above, we find that in this instance it is unlikely that Siliq will cause confusion with the over-the-counter product Salic-2, as it appears that the product is not marketed.
3.	Salac	70	Dose: 210 mg vs. Apply to the affected area or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Other: Salac is a discontinued OTC salicylic acid 2% topical liquid formulation with branded equivalents available.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
4.	Symlin	55
5.	Sular	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
6.	Sildec DM	64	Dose: 210 mg vs. xx mL or xx tsp Orthographic: The lengths of the names differ by more than two letters (including the modifier 'DM'). The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of the root names sound different.
7.	Philith	60	Dose: 210 mg vs. 1 tablet Orthographic: The lengths of the names differ by two letters. The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The beginning and ending consonant sounds in the names sound different.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
8.	Salex	60	Dose: 210 mg vs. Apply to the affected area or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences.
9.	Silace	60	Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
10.	Liq-10	59	Dose: 210 mg vs. xx mL or xx tsp Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: Although both names have 2 syllables, the same sounding letter string 'liq' are in opposite syllables. Therefore, the names sound different when spoken.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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.	Selrx	57	Dose: 210 mg vs. Apply to the scalp or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
12.	(b) (4)		
13.	Saleto Note: Discontinued ibuprofen product with generic equivalents available.	56	Dose: 210 mg vs. xx mg or xx tabs Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Saleto contains an extra syllable. The second and third syllables of this name pair sound different. Other: Multiple branded and generic ibuprofen products are available. HCP would likely prescribe a marketed brand product or by the well know generic name 'ibuprofen'.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
14.	Solia Note: Discontinued product with branded and generic equivalents available.	56	Dose: 210 mg vs. 1 tablet or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
15.	Belviq	54	Dose: 210 mg vs. 10 mg or 1 tablet Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different.
16.	Silphen	54	Dose: 210 mg vs. xx mL or xx tsp Orthographic: The lengths of the names differ by two letters. The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
17.	Sulfac Note: Discontinued product with branded and generic equivalents available.	54	Dose: 210 mg vs. xx drops or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
18.	Syllact Note: Discontinued product with branded and generic equivalents available.	54	Dose: 210 mg vs. xx scoops or xx tbsp Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
19.	Salitop Note: Discontinued product with branded and generic equivalents available.	52	Dose: 210 mg vs. Apply to the affected area or UAD Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Salitop contains an extra syllable. The second/third syllables of this name pair sound different.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
20.	Sele-Pak Note: Discontinued product with generic equivalents available.	52	Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Sele-Pak contains an extra syllable. The second/third syllables of this name pair sound different.
21.	Selseb Note: Discontinued product with generic equivalents available.	52	Dose: 210 mg vs. Apply to the scalp or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
22.	Silafed	52	Dose: 210 mg vs. xx mL or xx tsp Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Silafed contains an extra syllable. The second/third syllables of this name pair sound different.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
23.	Skelex Note: Discontinued product with branded and generic equivalents available.	52	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different.
24.	Silapap	51	Dose: 210 mg vs. xx mL or xx tsp Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Silapap contains an extra syllable. The second/third syllables of this name pair sound different.
25.	Slow-K Note: NDA 017476 was withdrawn FR effective as 6/18/2009. Branded and generic equivalents available.	51	Dose: 210 mg vs. 8 mg or xx tablets Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The names sound different.

No.	**Proposed name: Siliq** **Established name: Brodalumab** **Dosage form: Injection** **Strength(s):** 210 mg Pre-filled syringe **Usual Dose:** 210 mg given weekly for the first 3 weeks, and then every 2 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**
26.	Solv X	50	Dose: 210 mg vs. Apply to scalp or UAD Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
27.	**Soulus** Rp	50	Dose: 210 mg vs. Apply to affected area or UAD Orthographic: The lengths of the names differ by more than two letters (including the modifier 'Rp').The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
28.	Surelac Note: Discontinued product with branded and generic equivalents available.	50	Dose: 210 mg vs. 3000 units or xx tablets Orthographic: The lengths of the names differ by two letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

N/A

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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
29.	Solis	69	International diazepam product formerly marketed in United Kingdom.
30.	(b) (4)		
31.	Silicon	62	Not a drug, but a pharmaceutical ingredient.
32.	Skelid	60	NDA 020707 was withdrawn FR effective as of 1/5/2015. No generic equivalents are available.
33.	Shellac	59	Not a drug, but a pharmaceutical ingredient.
34.	Suleo-C	58	International carbaryl product marketed in Singapore.
35.	Sil-tex	56	Discontinued cold/cough product with no generic equivalents available.
36.	Salpix	54	NDA 009008 was withdrawn FR effective as of 8/5/1996. No generic equivalents are available.
37.	Solian	54	International amisulpride product marketed in many countries.
38.	Sul-pak	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
39.	(b) (4)	54	Proposed proprietary name found unacceptable by DMEPA. ANDA 203595 was approved under the name Suclear.
40.	Zembrace (b) (4) ***	53	Proposed proprietary name for NDA 208223 withdrawn by the Applicant. The NDA was approved under the name Zembrace Symtouch.
41.	(b) (4)	53	Proposed proprietary name for ANDA 090468 found unacceptable by DMEPA. Subsequently, the proposed name Zyfrel*** was found acceptable by DMEPA.
42.	(b) (4)		
43.	Silybin	53	Milk thistle extract.
44.	**Sulf**-10 **Sulf**-15	53	ANDA 080025 was withdrawn FR effective as of 6/11/2007. Branded and generic equivalents available. ANDA 089047 was withdrawn FR effective as of 1/21/2004. No generic equivalents available.
45.	Sulla	52	NDA 016000 was withdrawn FR effective as 5/29/2002. No generic equivalents available.
46.	Sulmet	52	This is an animal drug.

No.	Name	POCA Score (%)	Failure preventions
47.	Salicin	50	International drug name for aspirin in Brazil.
48.	Salinex	50	Discontinued product with no generic equivalents available.
49.	Siladyl	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	Simplet	50	Discontinued product with no generic equivalents available.
51.	Simuc	50	Discontinued product with no generic equivalents available.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
52.	CIALIS	62
53.	DILEX	56
54.	V-CIL-K	56
55.	ACILAC	55
56.	DILT	54
57.	DYLIX	54
58.	FU LING	54
59.	A-CILLIN	52
60.	(b) (4)	52
61.	CYNVILOQ***	52

No.	Name	POCA Score (%)
62.	FLEET	52
63.	FLEX	52
64.	FOLBIC	52
65.	FOLEX	52
66.	FULYZAQ	52
67.	TOLAK	52
68.	V-CILLIN	52
69.	CHOLAC	50
70.	CYLATE	50
71.	CYLERT	50
72.	FOILLE	50
73.	ZYLET	50

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/s/

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02/26/2016

MISHALE P MISTRY
02/29/2016