CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207589Orig1s000

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:	August 06, 2015
Application Type and Number:	NDA 207589
Product Name and Strength:	Enstilar (calcipotriene and betamethasone dipropionate) Foam, 0.005%/0.064%
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Leo Pharma AS
Panorama #:	2015-574843
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Irene Chan, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name, Enstilar, was found conditionally acceptable in the IND[1]. The Applicant re-submitted the name, Enstilar, for review during the NDA cycle on May 29, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 29, 2015 proprietary name submission.

- Intended Pronunciation: [En-sti-lar]
- Active Ingredient: Calcipotriene and Betamethasone dipropionate
- Indication of Use: Topical treatment of plaque psoriasis in adults 18 years of age and older.
- Route of Administration: Topical
- Dosage Form: Foam
- Strength: 0.005%/0.064%
- Dose and Frequency: Apply to the affected area(s) once daily for up to 4 weeks.
- How Supplied: 1 x 60 g can and 2 x 60 g cans
- Storage: Store at 20°C – 25°C (68°F – 77°F); excursions permitted between 15°C – 30°C (59°F – 86°F)
- Container and Closure Systems: 156 mm height x 50 mm diameter glossy white aluminum can with clear inner (b) (4) fitted with a valve and actuator.

2 RESULTS

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

[1] Mena-Grillasca, C. Proprietary Review for Enstilar (IND 114063). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 DEC 20. RCM No.: 2013-1597.

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[2].

2.2.2 Components of the Proposed Proprietary Name

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

We note that the proposed proprietary name may evoke the medical term 'instill'. However, our concerns for medication errors are minimized by the fact that neither the formulation (i.e. foam) nor the packaging (i.e. 60 g can with actuator) resemble ophthalmic or otic products.

2.2.2.1 Dual Proprietary Name

The applicant, Leo Pharma, currently markets calcipotriene and betamethasone dipropionate ointment and topical suspension under the proprietary name Taclonex. However, for the foam formulation Leo Pharma is pursuing the proposed proprietary name Enstilar. Leo argues that Taclonex topical suspension was approved for the pediatric population (12 to 17 years of age) on August 2014. The estimated approval date for the foam formulation is October 2015. The temporal proximity of these expected approvals, and the anticipated attention on the pediatric indication, may increase the risk of off-label use of the foam formulation in pediatric patients if the name "Taclonex" is used.

In addition, Leo Pharma argues that Taclonex topical suspension is indicated for use up to 8 weeks; whereas the foam formulation will be indicated for use up to 4 weeks. Therefore, if the name Taclonex is used for the foam formulation prescribers and patients might confuse the products with the risk of the foam formulation being used beyond 4 weeks. Current clinical data does not support the safe use of the foam formulation for longer than 4 weeks or treatment. Finally, Leo Pharma indicates that they have identified 2 reports of medication errors in which the topical suspension was prescribed, but the ointment formulation was dispensed.

[2]USAN stem search conducted on July 28, 2015.

DMEPA considered the safety implications of having a dual proprietary name for this product line (i.e. concomitant administration leading to over dose). However, the risk of concomitant administration of Enstilar with Taclonex is no different from the risk of concomitant administration of Enstilar with any of the multiple calcipotriene and betamethasone dipropionate products currently available (branded and generics). Therefore, a distinct proprietary name for Leo's calipotriene and betamethasone topical foam formulation is acceptable.

2.2.3 FDA Name Simulation Studies

Eighty-four practitioners participated in DMEPA's prescription studies. 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 verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 10, 2015 e-mail, the Division of 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[3] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	132
Low similarity name pair: combined match percentage score ≤49%	0

[3] POCA search conducted on July 27, 2015.

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

Our analysis of the 134 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Division of Dermatology and Dental Products (DDDP) via e-mail on July 31, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DDDP on August 3, 2015, they stated no additional concerns with the proposed proprietary name, Enstilar.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any 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, Enstilar, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your May 29, 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.

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. [4]

***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)).
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.

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

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 do 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.

<table>
<tr><td></td><td colspan="2">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</td></tr>
<tr><td rowspan="2">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>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. Enstilar Study (Conducted on June 19, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Enstilar Apply to affected area once daily Outpatient Prescription: Enstilar use as directed #1	Enstilar Use as Directed Disp. #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 7/28/2015

245 People Received Study
84 People Responded

Study Name: Enstilar

Total	32	25	27	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
AMSTILA	0	1	0	1
ANSTALAR	0	1	0	1
EMSTELAR	0	1	0	1
ENATILAR	3	0	0	3
ENSTALAR	0	4	0	4
ENSTALARD	0	1	0	1
ENSTELAR	0	3	0	3
ENSTELLAR	0	6	0	6
ENSTIFAR	0	0	1	1
ENSTILAR	23	1	24	48
ENSTILAS	0	0	2	2
ENSTILER	1	0	0	1
ENSTILOR	5	0	0	5
ENSTYLAR	0	1	0	1
ESTORLA	0	1	0	1
INSTALLAR	0	2	0	2
INSTILLAR	0	1	0	1
INSTULAR	0	1	0	1
MSTARLA	0	1	0	1

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

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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.	Enstilar	100	Name subject of this review.
2.	Insta-Char	72	Orthographic: The infixes of this of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Other: Insta-Char is the family name for an over the counter product line of oral poison adsorbent products (i.e. Insta-Char aqueous base, Insta-Char aqueous base cherry, and Insta-Char sorbitol base). A prescription would need to include specific information to identify the product.

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 (%)
3.	Oxtellar XR	66
4.	Sensipar	62
5.	Stelara	62
6.	Instacort	58
7.	Entecavir	57
8.	Zemplar	57

No.	Name	POCA Score (%)
9.	Nicolar Note: Discontinued product, but branded and generic equivalents are available.	56
10.	Sular	53
11.	Estazolam	52
12.	Epiflur	51
13.	Tafinlar	50
14.	(b) (4) ***	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:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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**
15.	Endolor Note: Discontinued product, but other branded and generic products are available.	66	Dose: Apply to affected area or UAD vs. 1 or 2 capsules Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
16.	Constilac	64	Dose: Apply to affected area or UAD vs. xx mL Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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.	Ketalar	58	Dose: Apply to affected area or UAD vs. xx mg Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different.
18.	Constulose	56	Dose: Apply to affected area or UAD vs. xx mL or xx tsp Orthographic: The prefixes, suffixes, and length of this name pair have sufficient orthographic differences. Phonetic: The first and third syllables of this name pair sound different.
19.	Entex LA Note: Discontinued product with generic equivalents available.	56	Dose: Apply to affected area or UAD vs. xx cap or xx tab Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: Entex LA contains an extra syllable.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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.	Ponstel	56	Dose: Apply to affected area or UAD vs. xx cap or xx mg Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Enstilar contains an extra syllable.
21.	Synalar	55	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
22.	Cinolar Note: Discontinued product with generic equivalents available.	54	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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.	Elspar	54	Dose: Apply to affected area or UAD vs. xx International Units or IU Orthographic: The prefixes, infixes, and length of this name pair have sufficient orthographic differences. Phonetic: Enstilar contains an extra syllable.
24.	Emcin Clear Note: Discontinued product with branded and generic equivalents available.	54	Orthographic: The prefixes, infixes, and length of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.
25.	Execlear-C	54	Dose: Apply to affected area or UAD vs. xx mL or xx tsp Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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.	Neo-Synalar	54	Orthographic: The prefixes, infixes, and length of this name pair have sufficient orthographic differences. Phonetic: Neo-Synalar contains an extra syllable.
27.	Entsol	53	Orthographic: The infixes, suffixes, and length of this name pair have sufficient orthographic differences. Phonetic: Enstilar contains an extra syllable.
28.	Estarylla	53	Orthographic: The infixes, suffixes, and length of this name pair have sufficient orthographic differences. Phonetic: Estarylla contains an extra syllable.
29.	Remular	53	Dose: Apply to affected area or UAD vs. xx mg or xx tabs Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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**
30.	Acular	52	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
31.	Encare	52	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Enstilar contains an extra syllable.
32.	Extina	52	Orthographic: The suffixes and length of this name pair have sufficient orthographic differences. Phonetic: The first and third syllables of this name pair sound different.
33.	[redacted]	[redacted]	[redacted] (b) (4)

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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**
34.	Stivarga	52	Dose: Apply to affected area or UAD vs. xx mg or xx tabs Orthographic: The capital letter 'E' in Enstilar, infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The names sound different.
35.	Tensilon Note: Discontinued product with an equivalent branded product available.	52	Dose: Apply to affected area or UAD vs. xx mg or xx mL Orthographic: The capital 'T' in Tensilon and the infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.
36.	Basaglar	51	Dose: Apply to affected area or UAD vs. xx Units Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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**
37.	Estra-V40	51	Dose: Apply to affected area or UAD vs. xx mg Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: Enstilar contains an extra syllable over the root name Estra. The name Estra-V40 contains two extra syllables over Enstilar.
38.	Menstridol	51	Dose: Apply to affected area or UAD vs. xx tab Orthographic: The capital letter 'M' and the suffixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different.
39.	Ed-Spaz	50	Dose: Apply to affected area or UAD vs. xx mg or xx tab Orthographic: The names look different when scripted. Phonetic: The names sound different.

No.	**Proposed name:** Enstilar **Established name:** calcipotriene and betamethasone dipropionate **Dosage form:** Foam **Strength(s):** 0.005%/0.064% **Usual Dose:** Apply to the affected area(s) once daily.	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**
40.	Eskalith CR Note: Discontinued product with generic equivalents available.	50	Dose: Apply to affected area or UAD vs. xx mg or xx tab Orthographic: The names look different when scripted. Phonetic: The names sound different.
41.	Estraderm	50	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.
42.	Exparel	50	Dose: Apply to affected area or UAD vs. xx mg or xx mL Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.

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

Not applicable

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
43.	Indolar	68	Trade name for indomethacin in the United Kingdom.
44.	Angitil SR	62	Trade name for diltiazem hydrochloride in the United Kingdom.
45.	Instillagel	62	Trade name for lidocaine hydrochloride and chlorhexidine gluconate in various foreign countries.
46.	Stimlor	62	Discontinued foreign trade name for naftidrofuryl oxalate.
47.	Estar	60	Name identified in RxNorm database.
48.	Vetalar	60	Unable to find product characteristics in commonly used drug databases.
49.	Entex ER	58	Discontinued product with no generic equivalents available.
50.	Masti-Clear	58	This is a veterinary drug.
51.	Topilar		Discontinued foreign trade name for fluclorolone acetonide.
52.	Doxylar	57	Trade name for doxycycline hyclate in the United Kingdom.
53.	Indolar SR	57	Trade name for Indomethacin in the United Kingdom.
54.	Apstil	56	Discontinued foreign trade name for diethylstilbestrol.

No.	Name	POCA Score (%)	Failure preventions
55.	Sensi-Care	56	Sensi-Care is the family name for an over the counter product line of skin care products to help manage skin compromised by exposure to and caustic stool residue (i.e. Sensi-Care Moisturizing Body Cream, Sensi-Care Perineal/Skin Cleanser, Sensi-Care Protective Barrier, Sensi-Care Body Wash and Shampoo, and Sensi-Care Clear Zinc). A prescription would need to include specific information to identify the product.
56.	Winstrol	54	Discontinued product with no generic equivalents available. NDA 012885 is Withdrawn FR Effective 8/20/2010.
57.	Epiklor	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
58.	Dialar	52	Trade name for diazepam in the United Kingdom.
59.	Eescula	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Enaprilat	52	
61.	Estrate LA	52	
62.	Exterol	52	Foreign trade name for urea hydrogen peroxide.
63.	Instafresh	52	This is not a drug, but an over-the-counter hand sanitizer.
64.	Optil SR	52	Foreign trade name for diltiazem hydrochloride.
65.	Erythrolar	51	Trade name for erythromycin in India.
66.	Ibular	51	Discontinued foreign trade name for ibuprofen.
67.	Sulfalar	51	Discontinued product with no generic equivalents available. ANDA 084955 is Withdrawn FR Effective 1/7/1992.

No.	Name	POCA Score (%)	Failure preventions
68.	Ed A-Hist LA	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
69.	Ensulizole	50	This is not a drug, but an ingredient in OTC sunscreens and anti-aging products.
70.	Estinyl	50	Discontinued product with no generic equivalents available. NDA 005292 is Withdrawn FR Effective 6/4/2004.
71.	Estra-D	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	(b) (4)		
73.	Ostilox	50	This is a veterinary drug.
74.	Tensopril	50	Trade name for lisinopril in India and Israel.

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

No.	Name	POCA Score (%)
75.	INDICLOR	63
76.	MENOSTAR	62
77.	FANSIDAR	60
78.	PENTOLAIR	60
79.	ANSPOR	59
80.	VANSPAR	58
81.	ANTEPAR	57

No.	Name	POCA Score (%)
82.	ANOLOR	56
83.	ANTIVERT	56
84.	ISTALOL	56
85.	NOSTRILLA	56
86.	TENCHLOR	56
87.	WE MIST II LA	56
88.	INSULASE	55
89.	OPTIVAR	55
90.	(b) (4) ***	55
91.	ALTAFLOR	54
92.	DENTI CARE	54
93.	DENTICARE	54
94.	GERMSTAR	54
95.	INSPRA	54
96.	ISOCLOR	54
97.	LUNESTAR	54
98.	ND CLEAR	54
99.	RESFLOR	54
100.	WE MIST LA	54
101.	ABSTRAL	53
102.	AXID AR	53
103.	ONSIOR	53
104.	TESTOMAR	53
105.	ANATUSS LA	52
106.	ANGILOL	52
107.	ANTILIRIUM	52
108.	ANTIZOL	52
109.	ASCLERA	52
110.	ASTELIN	52
111.	DOANS PILLS	52

No.	Name	POCA Score (%)
112.	(b) (4) ***	52
113.	INDINAVIR	52
114.	INDOCID R	52
115.	INSULIN	52
116.	IPSTYL	52
117.	(b) (4) ***	52
118.	(b) (4) ***	52
119.	ONY-CLEAR	52
120.	(b) (4) ***	52
121.	(b) (4) ***	52
122.	DILOR	51
123.	OPTICLEAR	51
124.	OPTI-CLEAR	51
125.	ASPI-COR	50
126.	DESTOLIT	50
127.	GENFIBER	50
128.	HER STYLE***	50
129.	(b) (4) ***	50
130.	INOSITOL	50
131.	ISCAR	50
132.	ONCASPAR	50
133.	TESTRO-L.A.	50
134.	TRELSTAR	50

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/s/

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