CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210797Orig1s000

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:	March 27, 2019
Application Type and Number:	NDA 210797
Product Name and Strength:	Scenesse (afamelanotide) implant, 16 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Clinuvel, Inc.
Panorama #:	2017-17475514-1
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Scenesse, 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. Clinuvel, Inc. did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Clinuvel, Inc. previously submitted the proposed proprietary name, Scenesse*** on May 5, 2010 to the IND. The name was found conditionally acceptable on October 21, 2010[a].

Clinuvel, Inc. resubmitted the name, Scenesse, for review on August 7, 2017 (IND) and September 11, 2017 (NDA). The name was found conditionally acceptable on December 5, 2017[b]. NDA 210797 was filed on November 8, 2018. This review is to reassess the proposed proprietary name, Scenesse. We note that all product characteristics remain the same.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 11, 2017.

- Intended Pronunciation: sē-nĕs'
- Active Ingredient: afamelanotide
- Indication of Use: (b) (4) in adult patients
- Route of Administration: subcutaneous
- Dosage Form: implant
- Strength: 16 mg
- Dose and Frequency: 1 implant subcutaneously every 2 months when required for photoprotection
- How Supplied: one pack of one single-dose Type I amber glass vial sealed with a PTFE coated rubber stopper containing a solid white to off-white rod approximately 1.7 cm in length and (b) (4) mm in diameter
- Storage: Store in a refrigerator at 2˚C - 8˚C (36°F - 46°F)

2 RESULTS

[a] Hamilton-Stokes, D. Proprietary Name Review for Scenesse (IND 103131). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2010 OCT 13. Panorama No. 2010-1044.

[b] Mena-Grillasca, C. Proprietary Name Review for Scenesse (IND 103131 and NDA 210797). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 05. Panorama No. 2017-16834383 and 2017-17475514.

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

2.1 SAFETY ASSESSMENT

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

2.1.1 United States Adopted Names (USAN) Search

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

2.1.2 FDA Name Simulation Studies

One hundred and two (n=122) practitioners participated in DMEPA's prescription studies for Scenesse. 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.

2.1.3 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 150 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 18 names not previously analyzed. These names are included in Table 1 below.

2.1.4 Names Retrieved for Review Organized by Name Pair Similarity

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

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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	10
Low similarity name pair: combined match percentage score ≤54%	8

[c] USAN stem search conducted on January 28, 2019.

[d] POCA search conducted on January 23, 2019 in version 4.3.

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

Our analysis of the 18 names contained in Table 1 determined none of the names will pose a risk for confusion with Scenesse as described in Appendices C through H.

2.1.6 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 March 15, 2019. 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 (DDDP) on March 20, 2019, they stated no additional concerns with the proposed proprietary name, Scenesse.

3 CONCLUSION

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

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

3.1 COMMENTS TO CLINUVEL, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 11, 2017, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

***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[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[f] 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.

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 ≥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.

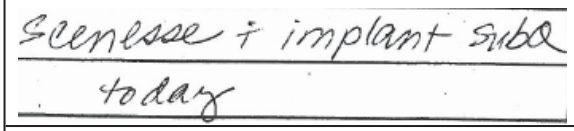
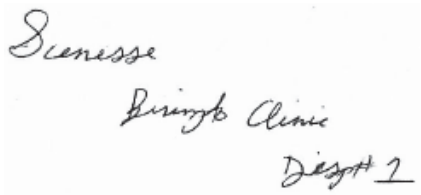
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 B: Prescription Simulation Samples and Results

Figure 1. Scenesse Study (Conducted on February 12, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Scenesse Bring to clinic. Dispense # 1
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

282 People Received Study
102 People Responded

Study Name: Scenesse

Total	24	57	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
C NEST	0	1	0	1
CEENES	0	1	0	1
CEENEST	0	1	0	1
CENAS	0	1	0	1
CENEF	0	2	0	2
CENES	0	2	0	2
CENESS	0	4	0	4
CENEST	0	3	0	3
CINEF	0	1	0	1
CINES	0	1	0	1
CINESS	0	3	0	3
CINEST	0	1	0	1

CNES	0	1	0	1
CNESS	0	1	0	1
C-NEST	0	1	0	1
FINESSE	0	2	0	2
SCANESSE	1	0	0	1
SCENESSE	14	1	21	36
SCINESS	0	1	0	1
SEANES	0	2	0	2
SEANESS	0	2	0	2
SEANEST	0	1	0	1
SEENEF	0	1	0	1
SEENES	0	2	0	2
SEENESS	0	4	0	4
SEENEST	0	2	0	2
SEENIF	0	1	0	1
SENEPH	0	1	0	1
SENES	0	1	0	1
SENESS	0	3	0	3
SENESSE	0	1	0	1
SENEST	0	2	0	2
SENISS	0	1	0	1
SIENESSE	4	0	0	4
SINEF	0	1	0	1
SINES	0	1	0	1
SINESSE	1	0	0	1
SINEST	0	1	0	1
SUNESSE	4	0	0	4
ZEANEST	0	1	0	1
ZENESS	0	1	0	1

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

No.	**Proposed name:** Scenesse **Established name:** afamelanotide **Dosage form:** implant **Strength(s):** 16 mg **Usual Dose:** 1 implant every 2 months subcutaneously	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.	Not Applicable (N/A)	N/A	N/A

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

No.	Name	POCA Score (%)
2.	N/A	N/A

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

No.	**Proposed name:** Scenesse **Established name:** afamelanotide **Dosage form:** implant **Strength(s):** 16 mg **Usual Dose:** 1 implant every 2 months subcutaneously	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**
3.	N/A	N/A	N/A

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

No.	Name	POCA Score (%)
4.	Canesten	54
5.	Sina-12X	54
6.	(b) (4) ***	53
7.	Refenesen	53
8.	Ceresin	52
9.	Celestone	50
10.	Enskyce	50
11.	Sinucleanse	50

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
12.	(b) (4) ***	64	Proposed proprietary name withdrawn by the Applicant. Product approved under the proprietary name Balcoltra
13.	(b) (4) ***	62	(b) (4)
14.	(b) (4) ***	62	
15.	Aminess 5.2	57	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
16.	Semax	57	International product formerly marketed in Chile.

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

No.	Name	POCA Score (%)
17.	Ceteth-3	56
18.	Ceteth-5	56

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

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/s/

MADHURI R PATEL
03/27/2019 02:04:30 PM

SEVAN H KOLEJIAN
03/27/2019 02:23:03 PM

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:	December 5, 2017
Application Type and Number:	IND 103131 NDA 210797
Product Name and Strength:	Scenesse (afamelanotide) Implant, 16 mg
Product Type:	Single Ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Clinuvel Inc.
Panorama #:	2017-16834383 2017-17475514
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Team Leader:	Sarah K. Vee, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Scenesse, 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 proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Scenesse on May 5, 2010 to the IND. The name was found conditionally acceptable on October 21, 2010.[a]

The Applicant resubmitted the name, Scenesse, for review on August 7, 2017 (IND) and September 11, 2017 (NDA). We note that the product characteristics have not changed since our original review on October 21, 2010.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 11, 2017 proprietary name submission.

- Intended Pronunciation: sē-nĕs'
- Active Ingredient: afamelanotide
- Indication of Use: (b) (4) in adult patients with erythropoietic protoporphyria (EPP).
- Route of Administration: Subcutaneous
- Dosage Form: Implant
- Strength: 16 mg
- Dose and Frequency: One implant subcutaneously every 2 months. (b) (4)
- How Supplied: Packaged individually in a glass vial sealed with a rubber stopper.
- Storage: Must be stored in a refrigerator at 2-8°C in its original package

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. The Division of Medication Error Prevention and Analysis (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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Scenesse, aims to address afamelanotide's pharmacological ability to reduce the oxidative damage to the epithelium and therefore minimize photoaging by offering photoprotection. 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.

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[a] Hamilton-Stokes, D. Proprietary Name Review for Scenesse (IND 103131). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); . RCM No. 2010-1044.

[b] USAN stem search conducted on September 30, 2017.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 24, 2017 and September 20, 2017 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.

2.2.4 FDA Name Simulation Studies

Sixty-nine (n=69) 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 134 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.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Scenesse will be available in 16 mg strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names with strength overlap and potential orthographic, spelling, and phonetic similarities with Scenesse that were not identified in POCA include Portrazza. This name is included in Table 1 below. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	5
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	129
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 135 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 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 November 30, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DDDP on December 5, 2017, they stated no additional concerns with the proposed proprietary name, Scenesse.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 11, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[c] POCA search conducted on September 27, 2017 in version 4.2.

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 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]

***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

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

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 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

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

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?

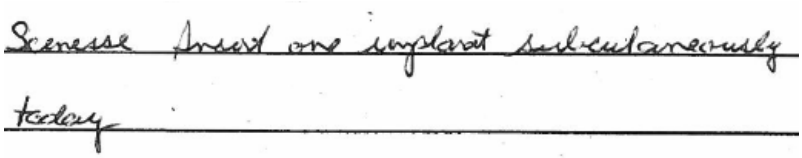
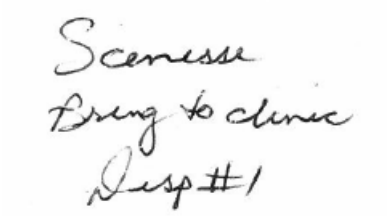
Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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 B: Prescription Simulation Samples and Results

Figure 1. Scenesse Study (Conducted on August 30, 2017)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Scenesse Bring to clinic. Dispense 1
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 9/30/2017

291 People Received Study
69 People Responded

Study Name: Scenesse

Total	23	24	22	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CEANESS	0	1	0	1
CENESS	0	2	0	2
CENESSE	0	3	0	3
CIENESS	0	1	0	1
C-NESS	0	2	0	2
CNEST	0	1	0	1
SANISSE	1	0	0	1
SCANESSI	1	0	0	1
SCENESE	1	0	0	1
SCENESEE	0	0	1	1
SCENESSA	1	0	0	1
SCENESSE	14	0	20	34
SCENESSE SMART ONE IMPLANT	0	0	1	1
SCENESSI	1	0	0	1
SCENISSE	1	0	0	1
SCENISSI	1	0	0	1
SCENNESE	1	0	0	1
SCENUSSA	1	0	0	1
SEAMIST	0	1	0	1
SEANES	0	1	0	1
SEANESS	0	1	0	1
SEANESSE	0	1	0	1
SEENESS	0	3	0	3
SEENUS	0	1	0	1
SENAS	0	1	0	1
SENESSE	0	1	0	1
SENYS	0	1	0	1
SINESE	0	1	0	1
SINESS	0	1	0	1
SINESSE	0	1	0	1

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

No.	**Proposed name: Scenesse** **Established name: afamelanotide** **Dosage form: implant** **Strength(s): 16 mg** **Usual Dose: 1 implant every 2 months**	**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.	Scenesse	100	Name subject of this review.
2.	Renese	79	Discontinued polythiazide product with no generic equivalents available. NDA 012845 status is withdrawn FR effective 6/18/2009.
3.	Senna S	74	Orthographic: The length of the root names (8 letters vs. 5 letters), additional letters 'c' and ending 'e' in Scenesse, and the modifier S present in Senna S help differentiate the names. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Frequency of administration: every 2 months vs. once or twice daily Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senna S in an over-the-counter laxative.
4.	Panase	70	Discontinued amylase/lipase/protease product with no generic equivalents available.
5.	Simpesse	70	Orthographic: Simpesse has a down stroke letter ('p') that is not present in Scenesse and helps differentiate the names. Phonetic: The first syllables of this name pair sound different. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Frequency of administration: every 2 months vs. once daily Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Simpesse is an oral contraceptive.

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 (%)
6.	Sinemet	65
7.	Isentress	63
8.	Linzess	61
9.	Tenex	60
10.	Cena K Note: Discontinued potassium chloride product with generic equivalents available.	60
11.	Menest	60

No.	Name	POCA Score (%)
12.	Syntest Note: Discontinued esterified estrogens/methyltestosterone product with branded and generic equivalents available.	58
13.	Serzone Note: Discontinued nefazodone hydrochloride product with generic equivalents available.	55

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: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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.	Sinex	68	This name pair has sufficient orthographic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sinex is the root name of a line of over-the-counter (OTC) analgesic/decongestant products available as oral capsules and nasal sprays.
15.	(b) (4) ***	67	This name pair has sufficient orthographic and phonetic differences.
16.	Senox Note: Discontinued amoxicillin product with branded and generic equivalents available.		This name pair has sufficient orthographic differences. Dosage form: implant vs. capsule Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senox is a discontinued prescription antibiotic that would likely be prescribed by the established name, amoxicillin.
17.	Senatec Note: Discontinued lidocaine product with branded and generic equivalents available.	65	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. lotion Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senatec is a discontinued prescription topical anesthetic that would likely be prescribed by one of the better known brand names or the well-known established name, lidocaine.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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
18.	Clindesse	65	Orthographic: The prefixes 'Scen' vs. 'Clin' look different. In addition, Clindesse contains an upstroke letter 'd' in the infix of the name that is not present in Scenesse. Phonetic: The first syllables of this name pair sound different. Dosage form: implant vs. cream Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Clindesse is a prescription topical vaginal antibiotic.
19.	Silace	64	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. liquid Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Silace is an over-the-counter laxative.
20.	Scabene Note: Discontinued lindane product with generic equivalents available.	64	Orthographic: Scabene contains an upstroke letter 'b' in the infix of the name that is not present on Scenesse. This name pair has sufficient phonetic differences. Dosage form: implant vs. shampoo and lotion Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Scabene is a prescription product for the treatment of scabies.
21.	Enpresse	64	Orthographic: The prefixes 'Scen' vs. 'En' look different. In addition, Enpresse contains a down stroke letter 'p' in the infix of the name that is not present in Scenesse. This name pair has sufficient phonetic differences. Dosage form: implant vs. shampoo and lotion Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Enpresse is an oral contraceptive.
22.	Tenake Note: Discontinued acetaminophen/butalbital/caffeine product with branded and generic equivalents available.	62	Orthographic: The prefixes 'Sce' vs. Te' look different. In addition, Tenake has an upstroke letter ('k') in the suffix of the name that is not present in Scenesse. Dosage form: implant vs. capsule Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Tenake is an anti-migraine medication.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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.	Flonase	62	This name pair has sufficient orthographic differences. Phonetic: The first syllables 'Sce' vs. 'Flo' sound different. Dosage form: implant vs. shampoo and spray Route of administration: subcutaneously on the suprailiac crest vs. nasal Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Flonase is an over-the-counter allergy medication.
24.	Sebex	62	This name pair has sufficient orthographic differences. Dosage form: implant vs. shampoo Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sebex is an over-the-counter medicated shampoo.
25.	Fenesin Note: Discontinued guaifenesin product with branded and generic equivalents available.	62	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Fenesin is a discontinued prescription expectorant that would likely be prescribed by the well-known established name, guaifenesin.
26.	Genebs Note: Discontinued acetaminophen over-the-counter product with branded and generic equivalents available.	62	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Genebs is a discontinued over-the-counter analgesic that would likely be prescribed by the well-known branded name Tylenol, or the established name, acetaminophen.
27.	Vancenase Note: Discontinued beclomethasone dipropionate product with a branded equivalent available.	62	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. aerosol Route of administration: subcutaneously on the suprailiac crest vs. nasal Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Vancenase is an allergy medication.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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
28.	Centex Note: Discontinued guaifenesin/pseudoephedrine product with generic equivalents available.	60	This name pair has sufficient orthographic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Centex is an expectorant/decongestant medication.
29.	Conate Note: Discontinued docusate sodium product with branded and generic equivalents available.	60	This name pair has sufficient orthographic differences. Dosage form: implant vs. syrup Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Centex is an over-the-counter laxative.
30.	Selenos Note: Discontinued selenium sulfide product with generic equivalents available.	60	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. shampoo Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Selenos is an antiseborrheic, antifungal medication.
31.	Senosol-SS Note: Discontinued docusate sodium/sennosides product with branded and generic equivalents available.	60	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senosol-SS is an over-the-counter laxative.
32.	Sani-Clens Note: Discontinued glycerin/witch hazel product with branded and generic equivalents available.	60	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. pad Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sani-Clens is an over-the-counter hygienic cleansing pad.
33.	Tannate Note: Discontinued chlorpheniramine tannate/phenylephrine tannate/pyrilamine tannate product with a branded equivalent available.	59	This name pair has sufficient orthographic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Tannate is an antihistamine/decongestant.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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.	Sine-Aid IB	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sine-Aid IB is an analgesic/decongestant.
35.	Cenafed Note: Discontinued pseudoephedrine hydrochloride product with branded and generic equivalents available.	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet and syrup Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Cenafed is a decongestant.
36.	Sleep-Eze Note: Discontinued diphenhydramine hydrochloride product with branded and generic equivalents available.	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet and tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sleep-Eze is an antihistamine marketed as a sleeping aid.
37.	Sleep-Eze 3 Note: Discontinued diphenhydramine hydrochloride product with branded and generic equivalents available.	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet and tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sleep-Eze 3 is an antihistamine marketed as a sleeping aid.
38.	Xeneisol Note: Discontinued xenon xe 133 product with generic equivalents available.	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. gas Route of administration: subcutaneously on the suprailiac crest vs. inhalation
39.	Senosol Note: Discontinued sennosides product with branded and generic equivalents available.	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senosol is an over-the-counter laxative.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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.	Sarene	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. ointment Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sarene is an over-the-counter skin protectant.
41.	Senexon S	58	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senexon S is an over-the-counter laxative.
42.	Sennalax S	57	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sennalax S is an over-the-counter laxative.
43.	Aminess Note: Discontinued amino acids product with branded and generic equivalents available.	57	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. solution and tablet Route of administration: subcutaneously on the suprailiac crest vs. intravenous and oral.
44.	Cenolate Note: Discontinued ascorbic acid product with branded and generic equivalents available.	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. solution
45.	Senna Plus	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senna Plus is an over-the-counter laxative.
46.	Stingeze	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Stingeze is an over-the-counter product for insect bite relief.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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
47.	(b) (4)***	56	Orthographic: The prefixes 'Sce' vs. (b) (4) have sufficient orthographic differences. Phonetic: (b) (4) has an additional syllable. The first syllable in Scenesse and first/second syllables in L(b) (4)*** have sufficient phonetic differences. Dosage form: implant (b) (4) Route of administration: subcutaneously on the suprailiac crest vs. (b) (4) Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. (b) (4)
48.	Senna-Gen Note: Discontinued sennosides a and b product with branded and generic equivalents available.	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senna-Gen is an over-the-counter laxative.
49.	Desenex	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. spray Route of administration: subcutaneously on the suprailiac crest vs. topical Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Desenex is an over-the-counter antifungal.
50.	Senexon	56	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senexon is an over-the-counter laxative.
51.	Genasec Note: Discontinued acetaminophen/phenyltoloxamine citrate product with branded equivalents available.	56	Orthographic: The prefixes 'Sce' vs. 'Ge' have sufficient orthographic differences. This name pair has sufficient phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Genasec is an over-the-counter analgesic.

No.	Proposed name: Scenesse Established name: afamelanotide Dosage form: implant Strength(s): 16 mg Usual Dose: 1 implant every 2 months	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
52.	Senokot	55	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senokot is an over-the-counter laxative.
53.	Sinumed Note: Discontinued acetaminophen/chlorpheniramine maleate/pseudoephedrine hydrochloride product with branded equivalents available.	55	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Sinumed is an over-the-counter analgesic/antihistamine/decongestant product.
54.	Senna Soft Discontinued sennosides product with branded and generic equivalents available.	55	This name pair has sufficient orthographic and phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Senna Soft is an over-the-counter laxative.
55.	Trinessa	55	Orthographic: The prefixes 'Sce' vs. 'Tri' have sufficient orthographic differences. This name pair has sufficient phonetic differences. Dosage form: implant vs. tablet Route of administration: subcutaneously on the suprailiac crest vs. oral Setting of Use: Scenesse is indicated for a rare metabolic disorder and is administered exclusively by trained medical practitioners under aseptic conditions in a clinical setting. Trinessa is an oral contraceptive.

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

N/A

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

No.	Name	POCA Score (%)	Failure preventions
56.	4-cymene	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. p-Cymene was identified as an aromatic organic compound.
57.	Serenace	66	International haloperidol product marketed in various countries.
58.	Genesis	64	Not a human drug, but an animal drug.
59.	Congess	64	Discontinued guaifenesin/pseudoephedrine product with no generic equivalents available.

No.	Name	POCA Score (%)	Failure preventions
60.	Zymase	63	Discontinued amylase/lipase/protease product with no generic equivalents available.
61.	Geneyes	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
62.	Stannate	62	Not a drug. In chemistry, the term refers to compounds of tin (Sn).
63.	Sansert	62	Discontinued methysergide maleate product with no generic equivalents available.
64.	(b) (4)	62	Proposed proprietary name found acceptable by DMEPA, but later withdrawn by the Applicant. NDA 209022 was approved under the name Xhance.
65.	Serenus	60	Not a human drug, but an animal drug.
66.	Genesa	60	Discontinued arbutamine hydrochloride drug with no generic equivalents available.
67.	Cenestin	60	Discontinued estrogens, conjugated synthetic A drug with no generic equivalents available.
68.	Pheneen	59	Not a drug, but a disinfectant.
69.	Phenesin	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
70.	Seldane	59	Discontinued terfenadine product with no generic equivalents available.
71.	Phytase	58	Not a drug, but any type of phosphate enzyme that catalyzes the hydrolysis of phytic acid.
72.	Somnote	58	Discontinued chloral hydrate product with no generic equivalents available.
73.	Scopace	58	Discontinued scopolamine hydrobromide product with no generic equivalents available.
74.	Sinodec	58	Discontinued chlorpheniramine maleate/methscopolamine nitrate/phenylephrine product with no generic equivalents available.
75.	Sweet-Ease	58	Not a drug, but a sucrose solution.
76.	Sedivet	57	Not a human drug, but an animal drug.
77.	Phenzene	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
78.	Comtess	57	International entacapone product marketed in various countries.
79.	Sucrose	57	Not a drug, but an ingredient in some pharmaceutical products.
80.	Caseins	57	Not a drug, but proteins commonly found in mammalian milk.
81.	Rynessa	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
82.	Senatec HC	56	Discontinued hydrocortisone acetate/lidocaine hydrochloride product with no generic equivalents available.
83.	1-Decene	56	Not a drug. Decene is an alkene with the formula $C_{10}H_{20}$.
84.	Centussin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
85.	Renese-R	56	Discontinued polythiazide/reserpine product with no generic equivalents available.
86.	Congess Sr	56	Discontinued guaifenesin/pseudoephedrine hydrochloride product with no generic equivalents available.
87.	PhenyI-T	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
88.	Sinufed	55	Discontinued guaifenesin/pseudoephedrine hydrochloride product with no generic equivalents available.
89.	Selenite	55	Not a drug. Identified as Sodium Selenite powder for compounding.
90.	(b) (4) ***	55	Alternate name proposed for NDA 021945. The NDA was approved under the name Makena.
91.	Sensi-Care	55	Sensi-Care was found to be the name of a Crest sodium fluoride rinse and a moisturizing cream.

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 (%)
92.	Deanase	65
93.	Xerese	64
94.	Ceredase	64
95.	Tnkase	62
96.	Mannose	62
97.	Ventuss	62
98.	Phenasep	60
99.	Penntuss	60
100.	Certuss	60
101.	Eminase	60
102.	Evvese	59
103.	Kentace	58
104.	Tannate 12 S	58
105.	Bidnase	58
106.	Tencet	58
107.	Arsenate	58
108.	E-Base	58
109.	Zensa	58
110.	Beconase	58
111.	Cestex	58
112.	Chenix	57
113.	Ceteth-10	56
114.	Ceteth-16	56
115.	Ceteth-2	56
116.	Ceteth-20	56
117.	Ceteth-23	56
118.	Ceteth-24	56
119.	Ceteth-25	56
120.	Ceteth-7	56
121.	Ryneze	56
122.	Orinase	56
123.	Pain-Ease	56
124.	Kinerase	56
125.	Cesamet	56
126.	Discase	56
127.	Entre-S	56
128.	Dygase	55
129.	Hydase	55
130.	Tannic-12 S	55
131.	Tenuate	55

[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 (%)
132.	Glynase	55
133.	Rendells	55
134.	Caseinate	55
135.	Portrazza	10

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Medrol
2.	Boudreauxs
3.	Methylprednisolone
4.	ATACAND
5.	Perphenazine
6.	Galantamine Hydrobromide
7.	Hydromorphone Hydrochloride
8.	Galantamine
9.	Perphenazine
10.	Candesartan cilexetil
11.	ARRID XX Roll On
12.	Walgreens Original
13.	EXALGO
14.	Mineral Wear Talc-Free Mineral Liquid Foundation
15.	Candesartan
16.	BABYS BUTT AID
17.	EXALGO
18.	Old Spice Red Zone Collection Swagger
19.	Old Spice High Endurance Clear
20.	Gillette Endurance Clear Brisa Tropical
21.	Gillette Endurance Power Beads Cool Wave Clear
22.	Gillette Sport Power Rush Clear
23.	Gillette Sport Sport Triumph Clear
24.	Gillette Endurance Arctic Ice Clear
25.	Gillette Endurance Cool Wave Clear
26.	Gillette Sport Undefeated Clear
27.	Gold Bond Pain Relieving Foot
28.	Sure Original Solid Unscented
29.	Sure Original Solid Regular
30.	Sure Original Solid Fresh Scent
31.	Sure Original Solid Powder
32.	Sure Original Solid Fresh and Cool
33.	Levothyroxine
34.	Ricetsotox
35.	Dioscorea batata 16 Special Order
36.	Candesartan cilexetil
37.	RAZADYNE
38.	Dr.G Revital Enhancer Cleansing Foam
39.	Babys Butt Care Diaper Rash
40.	Norepinephrine Bitartrate
41.	Perphenazine
42.	Aruba Aloe Deodorant Men
43.	Aruba Aloe Deodorant Women

No.	Name
44.	Cold and Hot
45.	Methylprednisolone
46.	Candesartan Cilexetil
47.	PCXX 1.64 STANNOUS RNS MINT
48.	PCXX 1.64 STANNOUS RNSSTRAWBERRY
49.	ARRID XX Roll On
50.	IMADA FOUR SEASONS SAFE ANALGESIC BALM
51.	GABITRIL
52.	ChiRhoStim
53.	Secret Paris Romantic Rose Clear
54.	Secret Scent Expressions Clear Coconut Splash
55.	Secret Outlast Clear Protecting
56.	Secret Scent Expressions Clear So Very Summerberry
57.	Secret Scent Expressions Clear Va Va Vanilla
58.	Secret Scent Expressions Clear Ooh La La Lavender
59.	Secret Australia Eucalyptus Blossoms Clear
60.	Secret Brazil Rainforest Mist Clear
61.	Secret Hawaii Citrus Breeze Clear
62.	Secret Scent Expressions Truth or Pear Clear
63.	Secret Pasion de Tango Clear
64.	Secret Scent Expressions Sunny Citrus Clear
65.	Secret Scent Expressions Cabana Cool Clear
66.	Secret Bora Bora Fresh Orchid Clear
67.	Secret Outlast Active Fresh Clear
68.	Secret Outlast Clear Fresh Lotus
69.	Secret Capri Island Retreat Clear
70.	Gillette Endurance Ultimate Fresh Clear
71.	Secret Cool Waterlily Clear
72.	Secret Chill Ocean Clear
73.	Secret Classic Cocoa Butter Scent Clear
74.	Secret Va Va Vanilla Clear
75.	Secret Luxe Lavender Clear
76.	Secret Paris Rose Clear
77.	Secret Hawaii Citrus Clear
78.	Secret Wild Sugar Clear
79.	Secret Fresh Orchid Clear
80.	Gillette Endurance Wild Rain Clear
81.	Secret Active Cool Clear
82.	Yeast Ultra Deep Cleansing Whip Foam
83.	Obeo 7way Moisture
84.	Ultra-Technekow
85.	Aloe Soothing
86.	Cellbn First Care Cleanser

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/s/

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