CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208032Orig1s000

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 6, 2015
Application Type and Number:	NDA 208032
Product Name and Strength:	Kovanaze (tetracaine and oxymetazoline) nasal spray 3%/0.05%
Product Type:	Multi-ingredient combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	St. Renatus, LLC.
Panorama #:	2015-722507
DMEPA Primary Reviewer:	Millie Shah, PharmD, BCPS
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Kovanaze, 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, Kovanaze, on April 11, 2014. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Kovanaze, acceptable in OSE Review #2014-17224, dated September 2, 2014[1]. The Applicant proposes to package nasal sprays (b) (4) . The appropriateness of labeling and packaging will be addressed in a labeling and packaging review.

1.2 PRODUCT INFORMATION

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

- Intended Pronunciation: kō vă nāz
- Active Ingredient: tetracaine hydrochloride and oxymetazoline hydrochloride
- Indication of Use: Kovanaze is an ester local anesthetic with a vasoconstrictor indicated for regional anesthesia when performing a restorative procedure on teeth 4-13 and A-J.
- Route of Administration: intranasal
- Dosage Form: Nasal spray in pre-filled, single-use sprayer: 6 mg tetracaine HCl and 0.1 mg oxymetazoline HCl in each 0.2 mL spray
- Strength: 3%/0.05%
- Dose and Frequency:

Age Group	Dose
Adults (≥ 18 years old)	2 sprays (0.2 mL per spray), 4-5 minutes apart
	1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 minutes after the second spray
Children (b) (4)	2 sprays (0.2 mL per spray),

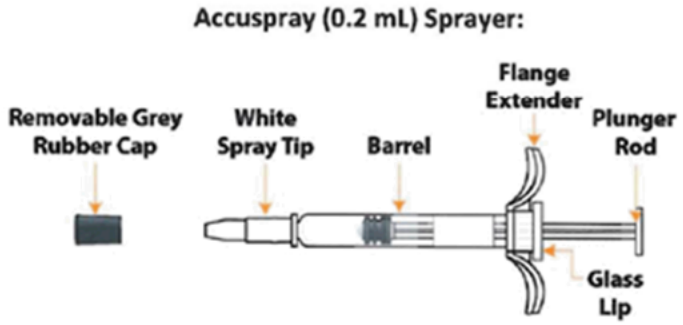
[1] Schlick J. Proprietary Name Review for Kovanaze (tetracaine and oxymetazoline) Nasal Spray (IND 070868). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 SEP 02. 25 p. OSE RCM No.: 2014-17224.

weighing ≥ 40 kg)	(b) (4)

- How Supplied: Kovanaze is supplied in pre-filled, single-use sprayers that deliver 0.2 mL per sprayer.
  - NDC 69803-100-10: Box of 30 sprayers (b) (4)

(b) (4)

- Storage: Store between 2° and 8°C (36° and 46°F); excursions permitted between 0° and 15°C (32° and 59°F) [see USP controlled cold temperature].
- Container and Closure Systems:



2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) 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]USAN stem search conducted on June 25, 2015.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Kovanaze, is a [redacted] (b) (4) Because healthcare providers administer the product nasally, we find this portion of the name acceptable. However, if the Applicant wishes to expand their product line in the future to other routes of administration, this may render the original proprietary name inaccurate.

2.2.3 *FDA Name Simulation Studies*

Sixty-nine practitioners participated in DMEPA's prescription studies. Of the 69 practitioners, 21correctly interpreted the name Kovanaze. 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 email dated, July 7, 2015, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) 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%	159
Low similarity name pair: combined match percentage score ≤49%	0

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

The proposed product, Kovanaze, will be available in strength of 3%/0.05%. Since this is not a typical strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Kovanze that were not identified in POCA, and found to have an overlap in strength with Kovanaze. Due to limitations in

[3] POCA search conducted on June 18, 2015.

this database, which is unable to search special characters such as "%," we searched 3 mg, 3 mL, 0.05 mg, and 0.05 mL. Our search identified the name Kariva, which has been evaluated in Appendix F.

Table 1A. (PR°PLLR™) **Search Results**	**POCA score**
Kariva	38

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

Our analysis of the 162 names contained in Table 1 and 1A determined 162 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on July 28, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAAAP on August 4, 2015, they stated no additional concerns with the proposed proprietary name, Kovanaze.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Lisa Skarupa, OSE project manager, at 301-796-2219.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Kovanaze, 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 DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

[4] 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 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.

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. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
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.

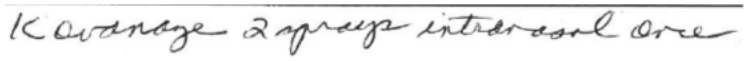
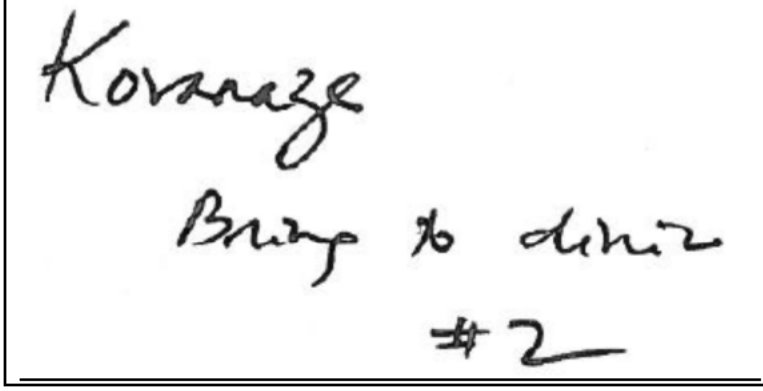
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤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. Kovanaze Study (Conducted on June 26, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Kovanaze Bring to clinic Dispense number two
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

245 People Received Study

69 People Responded

Study Name: Kovanaze

Total	22	24	23	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
COVANASE	0	3	0	3
COVANAZE	0	2	0	2
COVENACE	0	1	0	1
COVENASE	0	10	0	10
COVENAZ	0	1	0	1
COVENAZE	0	1	0	1
COVENEZ	0	1	0	1
COVINACE	0	2	0	2
COVINASE	0	3	0	3
KEVANAZE	0	0	1	1
KEVANOGE	0	0	1	1
KORANAZA	1	0	0	1
KORANAZE	2	0	0	2
KOVANAGE	0	0	10	10
KOVANAYE	0	0	2	2
KOVANAZE	16	0	5	21
KOVANAZOLE	0	0	1	1
KOVANGE	0	0	1	1
KOVANOYE	0	0	1	1

KOVANZE	0	0	1	1
KOVARAZE	3	0	0	3

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

No.	**Proposed name: Kovanaze** **Established name: tetracaine HCl and oxymetazoline HCl** **Dosage form: nasal spray** **Strength(s): 3%/0.05%** **Usual Dose:** **Age Group** / **Dose** Adults (≥ 18 years old) / 2 sprays (0.2 mL per spray), 4-5 min apart 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray (b) (4) weighing ≥ 40 kg) / 2 sprays (0.2 mL per spray), (b) (4) (b) (4)	**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.	Kovanaze	100	Name subject of this review
2.	Kogenate	70	The infixes and suffixes of this name pair have sufficient orthographic differences. The down-stroke in the letter "g" in the infix and the cross-stroke in the letter "t" in the suffix in Kogenate give the name pair a different shape when scripted. The second (-van- vs. –gen-) and last (-aze vs. –ate) syllables of the name pair sound different.There is no overlap in strength and/or dose between Kovanaze and Kogenate (available in 250, 500, 1,000, 2,000, and 3,000 IU single-use vials and dosed at 10 to 50 IU/kg IV once).

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 (%)
1.	Tolinase	65
2.	Novamine	59

No.	Name	POCA Score (%)
3.	Novamine 11.4%	59
4.	Novamine 15%	59
5.	Novamine 8.5%	59
6.	Trovan IV	59
7.	Lomanate	58
8.	Codamine	57
9.	Bromanate	56
10.	Kabikinase	56
11.	Kuvan	56
12.	Panase	56
13.	Colonaid	54
14.	Fovane	54
15.	Kogenate FS	54
16.	Konakion	53
17.	Sonazine	52
18.	Avanafil	51
19.	Opana ER	51
20.	Alphanate	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: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose:	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
	Age Group: Adults (≥ 18 years old) — Dose: 2 sprays (0.2 mL per spray), 4-5 min apart; 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Age Group: Children (b) (4), weighing ≥ 40 kg) — Dose: 2 sprays (0.2 mL per spray), (b) (4) (b) (4)		
1.	Patanase	62	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
2.	Povidone	62	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
3.	Solaraze	62	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	Betanate	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and last syllables of this name pair sound different.

No.	Proposed name: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose:	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
	Age Group: Adults (≥ 18 years old) — Dose: 2 sprays (0.2 mL per spray), 4-5 min apart; 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Age Group: Children (b) (4), weighing ≥ 40 kg) — Dose: 2 sprays (0.2 mL per spray), (b) (4) (b) (4)		
5.	Kinerase	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
6.	Tussinate	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
7.	Vancenase	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
8.	Voraxaze	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
9.	Ketamine	55	The prefixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.

No.	Proposed name: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose:	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
	Age Group: Adults (≥ 18 years old) — Dose: 2 sprays (0.2 mL per spray), 4-5 min apart; 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Age Group: Children (b) (4), weighing ≥ 40 kg) — Dose: 2 sprays (0.2 mL per spray), (b) (4) (b) (4)		
10.	Econazole	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and last syllables of this name pair sound different. Econazole has an extra syllable.
11.	Kepivance	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and last syllables of this name pair sound different.
12.	Konyne 80	54	The suffixes of this name pair have sufficient orthographic differences. The last syllables of this name pair sound different.
13.	Vanamide	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
14.	Allernaze	53	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	Proposed name: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose: Age Group: Adults (≥ 18 years old) — Dose: 2 sprays (0.2 mL per spray), 4-5 min apart; 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Age Group: Children (b) (4) weighing ≥ 40 kg) — Dose: 2 sprays (0.2 mL per spray) (b) (4) (b) (4)	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.	Brovana	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
16.	Erwinaze	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
17.	Karbinal	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and last syllables of this name pair sound different.
18.	Novantrone	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. Novantrone has 10 letters, whereas Kovanaze has 8 letters, giving it a shorter length when scripted. The first and last syllables of this name pair sound different.

No.	**Proposed name: Kovanaze** **Established name: tetracaine HCl and oxymetazoline HCl** **Dosage form: nasal spray** **Strength(s): 3%/0.05%** **Usual Dose:** **Age Group** / **Dose** Adults (≥ 18 years old) / 2 sprays (0.2 mL per spray), 4-5 min apart 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Children (b) (4), weighing ≥ 40 kg) / 2 sprays (0.2 mL per spray), (b) (4) (b) (4)	**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**
19.	Tanamine	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
20.	Vanacet	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
21.	Temovate	51	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
22.	Vandazole	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and last syllables of this name pair sound different.
23.	Folivane-F	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and last syllables of this name pair sound different.

No.	Proposed name: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose: Age Group: Adults (≥ 18 years old) — Dose: 2 sprays (0.2 mL per spray), 4-5 min apart; 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray Age Group: Children (b) (4), weighing ≥ 40 kg) — Dose: 2 sprays (0.2 mL per spray), (b) (4) (b) (4)	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
24.	Karbinal ER	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and last syllables of this name pair sound different.
25.	Ketozole	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and last syllables of this name pair sound different.
26.	Keveyis***	50	The suffixes of this name pair have sufficient orthographic differences. The last syllables of this name pair sound different.
27.	Kovia	50	The suffixes of this name pair have sufficient orthographic differences. Kovia has 5 letters, whereas Kovanaze has 8 letters, giving it a longer length when scripted. The last syllables of this name pair sound different.

No.	Proposed name: Kovanaze Established name: tetracaine HCl and oxymetazoline HCl Dosage form: nasal spray Strength(s): 3%/0.05% Usual Dose:	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
	<table><tr><th>Age Group</th><th>Dose</th></tr><tr><td>Adults (≥ 18 years old)</td><td>2 sprays (0.2 mL per spray), 4-5 min apart 1 additional spray (0.2 mL) if adequate anesthesia has not been achieved 10 min after the second spray</td></tr><tr><td>Children (b) (4) weighing ≥ 40 kg)</td><td>2 sprays (0.2 mL per spray), (b) (4) (b) (4)</td></tr></table>		
28.	Kutrase	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
29.	Sublimaze	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Kariva	38

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

No.	Name	POCA Score (%)	Failure preventions
1.	Kepvance	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Kera Nail	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Bovadine	59	Veterinary product
4.	Covace	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Kliovance	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Deanase	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Kentace	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Ovadine	56	Veterinary product

No.	Name	POCA Score (%)	Failure preventions
9.	(b) (4) ***	55	This is a secondary proposed proprietary name. The primary proposed proprietary name was found unacceptable by DMEPA (b) (4) Entire application (b) (4) withdrawn by the applicant.
10.	Kentovace	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Cophene B	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Cophene-X	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Davana oil	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Kebuzone	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Kerosene	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
16.	Fonazine	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Panakare	51	Veterinary product
18.	Panaleve	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Advantame	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Clavulanate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Kappadione	50	Product withdrawn from the market due to safety concerns. No therapeutic equivalents available. FR effective 3/2/94.
22.	K-lease	50	Product withdrawn from the market due to safety concerns. No therapeutic equivalents available. FR effective 9/15/98.
23.	Koromex	50	Product is not a drug but is a contraceptive diaphragm device.
24.	Nonanal	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
25.	Thiocyanate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Tusana D	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Orinase	59
2.	Hypaneze	58
3.	Povidine	58
4.	Eskornade	57
5.	Orabase	57
6.	Dovonex	56
7.	Or-Phen-Ade	56
8.	Pain-Eze	56
9.	Tolnate	56
10.	Caseinate	55
11.	Cocamine	55
12.	Colazide	55
13.	Desonate	55
14.	Beconase	54
15.	Catarase	54
16.	Collagenase	54

No.	Name	POCA Score (%)
17.	Conate	54
18.	Cortane	54
19.	Daranide	54
20.	Flonase	54
21.	Folnate	54
22.	Gadobenate	54
23.	Gladase	54
24.	Orphenate	54
25.	Toviaz	54
26.	Tybamate	54
27.	Cortane-B	53
28.	Protenate	53
29.	Serenace	53
30.	Stannate	53
31.	Buminate	52
32.	Calgonate	52
33.	Carafate	52
34.	Cardrase	52
35.	Carminate	52
36.	Carzenide	52
37.	Cobamamide	52
38.	Cobavite	52
39.	Contrave	52
40.	Convenia	52
41.	Glynase	52
42.	Hyteneze	52
43.	Quinate	52
44.	Tannate	52
45.	Tapazole	52
46.	Trandate	52

No.	Name	POCA Score (%)
47.	Cafatine	51
48.	Calamine	51
49.	Catalase	51
50.	Chlornade	51
51.	Clobevate	51
52.	Cotameth	51
53.	Equi-Nade	51
54.	Parnate	51
55.	Tocainide	51
56.	Travase	51
57.	Virazole	51
58.	Benzonate	50
59.	Bidnase	50
60.	Cinnamate	50
61.	Codafed	50
62.	Cold-Eeze	50
63.	Cortinide	50
64.	Cosamin	50
65.	Cutivate	50
66.	Dibunate	50
67.	Dopamine	50
68.	Dymenate	50
69.	Eminase	50
70.	Etofamide	50
71.	Ferronate	50
72.	Glibenese	50
73.	Morazone	50
74.	Neuramate	50
75.	Oxalate	50
76.	Peganone	50

No.	Name	POCA Score (%)
77.	Poviderm	50
78.	Povidex	50
79.	Provenge	50
80.	Solatene	50
81.	Tolazine	50
82.	Tramake	50
83.	Tri-Tannate	50
84.	Vasotate	50

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/s/

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08/06/2015

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