CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125513Orig1s000

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:	April 10, 2015
Application Type and Number:	BLA 125513
Product Name and Strength:	Strensiq (asfotase alfa) Injection 40 mg/mL and 100 mg/mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Alexion Pharmaceuticals
Submission Date:	January 15, 2015
Panorama #:	2015-47418
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Kendra Worthy, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Strensiq, 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 sponsor previously submitted the proposed proprietary name, Strensiq on December 21, 2012. DMEPA completed a proprietary name review for the proposed name, Strensiq, as a part of the evaluation of IND 100619. DMEPA found the proposed name to be conditionally acceptable.

Thus, the sponsor submitted the name, Strensiq, for review on January 15, 2015 as a part of the evaluation of BLA 125513.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 15, 2015 proprietary name submission.

- Intended Pronunciation: stren' sik
- Active Ingredient: asfotase alfa
- Indication of Use: (b) (4) therapy in patients with infantile- and juvenile-onset hypophosphatasia (HPP).
- Route of Administration: Subcutaneous Injection
- Dosage Form: Solution for subcutaneous injection
- Strength: 40 mg/mL concentration, available in the following strengths ((b) (4) (b) (4), 18 mg/0.45 mL, 28 mg/0.7 mL, and 40 mg/1 mL) and 100 mg/mL concentration, available in the following strength (80 mg/0.8 mL).
- Dose and Frequency: Recommended dosage regimen of Strensiq is 2 mg/kg of body weight administered subcutaneously three times per week, or a dosage regimen of 1 mg/kg of body weight administered six times per week. The maximum volume of subcutaneous injection is 1mL per injection.
- How Supplied: supplied as a sterile, non-pyrogenic, preservative free solution in a 2-mL single use glass vial as a clear, colorless to slightly yellow aqueous solution at a concentration of either 40 mg/mL or 100 mg/mL in a carton of one (1) or twelve (12) vials (in the strengths mentioned above).
- Storage: must be stored in the original carton until the time of use under refrigerated conditions at 2-8°C (36-46°F) and protected from light.
- Container and Closure Systems: See How Supplied.

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 Gastroenterology & Inborn Error Products (DGIEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

104 practitioners participated in DMEPA's prescription studies. There was one response that did overlap with a currently marketed product, specifically "SoluPrep," during the voice portion of the Rx Study. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 30, 2015 e-mail, the Division of Gastroenterology & Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

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

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[1]USAN stem search conducted on February 11, 2015.

[2] POCA search conducted on February 11, 2015.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	130
Low similarity name pair: combined match percentage score ≤49%	1

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

Our analysis of the 132 names contained in Table 1 determined 132 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology & Inborn Error Products (DGIEP) via e-mail on April 6, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on April 10, 2015, they stated no additional concerns with the proposed proprietary name, Strensiq.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 15, 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. [3]

[3] 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.

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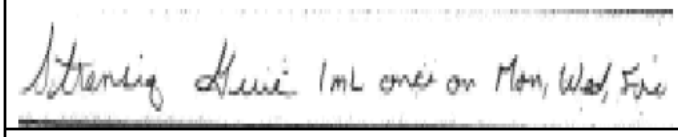
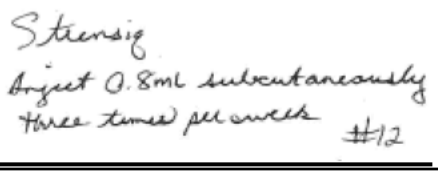
Appendix B: Prescription Simulation Samples and Results

Figure 1. Strensiq Study (Conducted on February 18, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Total	33	35	36	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ITRENSIG	0	0	1	1
SOLU PREP	0	1	0	1
STEENSIG	2	0	0	2
STEENSIQ	7	0	0	7
STENSIQ	1	0	1	2

STIENSIG	1	0	0	1
STIENSIQ	3	0	0	3
STRANSIQ	0	0	1	1
STREBIG	0	0	1	1
STREDVIK	0	1	0	1
STREDZICK	0	1	0	1
STRENDZIK	0	1	0	1
STRENSIA	0	0	1	1
STRENSIC	0	6	0	6
STRENSICK	0	1	0	1
STRENSIG	4	0	7	11
STRENSIG GUIE	0	0	1	1
STRENSIK	0	2	0	2
STRENSIQ	11	0	22	33
STRENSIQ GLUE	0	0	1	1
STRENSIX	0	1	0	1
STRENZIC	0	12	0	12
STRENZICK	0	2	0	2
STRENZIK	0	2	0	2
STRENZIQ	0	1	0	1
STREXIC	0	1	0	1
STRINSIQ	1	0	0	1
STRINZIX	0	1	0	1
STUNSIQ	3	0	0	3
TRENSIC	0	1	0	1

ZRENZIC	0	1	0	1

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

No.	**Proposed name: Strensiq** **Established name: asfotase alfa** **Dosage form: Solution for Subcutaneous Injection** **Strength(s): 40 mg/mL; 100 mg/mL** **Usual Dose: 2 mg/kg given subcutaneously 3x/week OR 1 mg/kg given subcutaneously 6x/week**	**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.	Strensiq***	100%	This name is the subject of the review.

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.	Proposed Name	POCA Score (%)
1.	Ferotrinsic	61%
2.	Star-Otic	58%
3.	Stiemycin	56%
4.	Stress Liquid	56%
5.	Strong Caps	55%
6.	Sucrets	54%
7.	Sucrets Ice	54%
8.	Dutrebis***	54%
9.	Sensipar	53%
10.	Astringyn	53%
11.	Estratest	53%
12.	Sansac	52%

13.	Schering PC4	52%
14.	Septra DS	52%
15.	Sitrex	52%
16.	Striverdi	52%
17.	Estrostep 21	52%
18.	Trezix	52%
19.	Satogesic	51%
20.	Psorent	51%
21.	Salutensin	50%
22.	Scrubs	50%
23.	Spastrin	50%
24.	Strazepam	50%
25.	Gastrinex	50%
26.	Trintex	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: Strensiq** **Established name: asfotase alfa** **Dosage form: Solution for Subcutaneous Injection** **Strength(s): 40 mg/mL; 100 mg/mL** **Usual Dose: 2 mg/kg given subcutaneously 3x/week OR 1 mg/kg given subcutaneously 6x/week**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Sprintec	68%	The last syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair has sufficient orthographic differences. This name pair has significant dosing differences: This name's usual dose is 1 tablet per day vs. Strensiq usual dose of 2 mg/kg given subcutaneously 3x /week or 1 mg/kg given subcutaneously 6x /week.
2.	Estrone AQ	62%	The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
3.	Spiretic	60%	This name contains more syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
4.	Striant	60%	The first and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
5.	Stridex	60%	The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic

			differences.
6.	Stridex	60%	The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
7.	Pitressin	60%	This name contains more syllables. The first syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
8.	Stagesic	59%	This name contains more syllables. The second syllable of this name pair has sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
9.	Stagesic-10	59%	This name contains more syllables. The second syllable of this name pair has sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
10.	Suprenza	58%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
11.	Stribild	57%	The last syllable of this name pair has sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
12.	Strix	57%	This name contains fewer syllables. Strensiq contains two or more letters than Strix. The first syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
13.	(b) (4) ***	54%	The first and last syllables of this name pair have sufficient phonetic differences.

			The suffix of this name pair has sufficient orthographic differences.
14.	Steri-stat***	54%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
15.	(b) (4) ***	54%	The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
16.	Estra AQ	54%	The first and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
17.	Estracyt	54%	This name contains more syllables. The suffix of this name pair has sufficient orthographic differences. This name pair has significant dosing differences: Estracyt usual dose is 4-6 capsules per day in divided doses vs. Strensiq usual dose of 2 mg/kg given 3x/week or 1 mg/kg given 6x/week
18.	(b) (4) ***	54%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
19.	Secretin	53%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
20.	Estrovis	53%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.

21.	Securon SR	52%	The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
22.	Strifon Fort	52%	This name contains more syllables. The second syllable of this name pair has sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
23.	(b) (4)***	52%	This name contains more syllables. The second and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
24.	Diatensec	52%	This name contains more syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
25.	Tresiba***	52%	This name contains more syllables. The second and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
26.	Smartfit***	51%	The first syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
27.	Suprofen	51%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
28.	Estro-Cyp	51%	This name contains more syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient

			orthographic differences.
29.	Estrogenic	51%	This name contains more syllables. The first and second syllables of this name pair have sufficient phonetic differences. The infix of this name pair has sufficient orthographic differences.
30.	Lotensin	51%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
31.	Photrexa***	51%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
32.	Scrub-Stat 2***	50%	The first and second syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
33.	Scrub-Stat 4***	50%	The first and second syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
34.	Sensi-Care	50%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
35.	Sporanox	50%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
36.	Staxyn	50%	The first and second syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient

			orthographic differences.
37.	Steritalc***	50%	This name contains more syllables. The first and last syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
38.	(b) (4) ***	50%	This name contains more syllables. The last syllable of this name pair has sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
39.	Sucrets DM	50%	The first syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
40.	Supress DX	50%	The first and second syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
41.	Sureclick***	50%	The first syllable of this name pair has sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
42.	Testro AQ	50%	The last syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
43.	Trental	50%	The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
44.	Soluprep	36%	This name contains more syllables. The first and second syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.

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

No.	Name	POCA Score (%)
1.	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
1.	Strongid	69%	For animal use only.
2.	Strongid T	64%	For animal use only.
3.	82 Strontium	64%	Unable to find product characteristics in commonly used drug-reference databases.
4.	85 Strontium	64%	Unable to find product characteristics in commonly used drug-reference databases.
5.	Strontium	64%	Unable to find product characteristics in commonly used drug-reference databases.

6.	Strontium-89	64%	Unable to find product characteristics in commonly used drug-reference databases.
7.	Streptase	62%	Application has been "revoked."
8.	(b) (4) ***	60%	Alternate proposed proprietary name. Primary proposed proprietary name, (b) (4) ***, found acceptable by DMEPA (b) (4) .
9.	Sensipak	56%	Unable to find product characteristics in commonly used drug-reference databases.
10.	Serentil	56%	Product Withdrawn for commercial reasons.
11.	Cornsilk	56%	Unable to find product characteristics in commonly used drug-reference databases.
12.	Estrogens	54%	Unable to find product characteristics in commonly used drug-reference databases.
13.	Sarenin	52%	Product Withdrawn per applicant's request in 1995
14.	Serenus	52%	For animal use only.
15.	Stiedex	51%	Unable to find product characteristics in commonly used drug-reference databases.
16.	Styrene	50%	Unable to find product characteristics in commonly used drug-reference databases.
17.	Tremin	50%	Product Withdrawn in 1992.

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

No.	Name	POCA Score (%)
1.	Droncit	61
2.	PRISTIQ	60
3.	CTx3 Rinse	56
4.	CTX4 Rinse	56
5.	Benziq	54
6.	BuTrans	54
7.	Prandin	53
8.	Premphase	53
9.	PREMPHASE 14/14	53
10.	QREDFORIQ	53
11.	Citravet	52
12.	Crantex	52
13.	(b) (4)	52
14.	Premique	52
15.	Prevacid	52
16.	Principen	52
17.	PRINCIPEN '125'	52
18.	PRINCIPEN '250'	52
19.	PRINCIPEN '500'	52
20.	PRINZIDE	52
21.	Progesic	52
22.	(b) (4)	52
23.	Triant-HC	52
24.	(b) (4)	52
25.	Pred-G S.O.P.	51
26.	Trancot	51
27.	TRYPSIN	51

28.	CERESIN	50
29.	COTRIM D.S.	50
30.	Denti-Rinse	50
31.	(b) (4)	50
32.	Fe-Tinic	50
33.	Fe-Tinic 150	50
34.	Nafrinse	50
35.	Pramotic	50
36.	Pre Milk	50
37.	PREPOPIK	50
38.	Targiniq	50
39.	Trandate	50
40.	TRASICOR	50
41.	Triacin C	50
42.	TRINALIN	50
43.	Trokendi	50
44.	Zestoretic	50

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/s/

MATTHEW J BARLOW
04/10/2015

KENDRA C WORTHY
04/10/2015

IRENE Z CHAN
04/13/2015