CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207958Orig1s000

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:	December 12, 2014
Application Type and Number:	NDA 207958
Product Name and Strength:	Spritam (levetiracetam) (b) (4) 250 mg, 500 mg, 750 mg and 1000 mg
Product Type:	Single product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Aprecia
Submission Date:	October 7, 2014
Panorama #:	2014-2257
DMEPA Primary Reviewer:	Lolita White, PharmD
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Spritam, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, Spritam on March 26, 2013 under IND 117613 and it was found to be acceptable in OSE Review #2013-843, dated Sept 23, 2013. The sponsor re-submitted the name, Spritam, for review on October 7, 2014 under NDA 207958.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 7, 2014 proprietary name submission.

- Intended Pronunciation: Spree' tam
- Active Ingredient: levetiracetam
- Indication of Use: Partial onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy and primary generalized tonic-clonic seizures.
- Route of Administration: Oral
- Dosage Form: (b) (4)
- Strength: 250 mg, 500 mg, 750 mg and 1000 mg.
- Dose and Frequency: 1000 mg per day given as divided doses. Additional dosing increments may be given to a maximum recommended daily dose of 3000 mg.
- How Supplied: Child-resistant blisters in cartons containing ten 6-count blister cards.
- Storage:
- 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 does not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) 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, Spritam 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.

2.2.4 FDA Name Simulation Studies

104 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. Common misinterpretations in the written prescription studies included mistaking the "i" for and "e" or the "m" for an "n". Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 17, 2014 email, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 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 external study conducted by (b) (4)

[1]USAN stem search conducted on 10/17/2014.

[2] POCA search conducted on 10/31/2014.

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%	250
Low similarity name pair: combined match percentage score ≤49%	3

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

Our analysis of the 255 names contained in Table 1 determined that none 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 Neurology Products (DNP) via e-mail on December 5, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on December 5, 2014, they stated no additional concerns with the proposed proprietary name, Spritam.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 7, 2014 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Spritam Study (Conducted on October 29, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Spritam 1g po BID Outpatient Prescription: Spritam 250mg Take 1 twice daily #60	Spritam 250mg take 1 twice daily dispense #60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Spritam

As of Date 10/30/2014

258 People Received Study

54 People Responded

Study Name: Spritam

Total	16	14	24	

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
SPINTAM	0	0	1	1
SPIRITAM	0	0	2	2
SPIRTAK	0	0	1	1
SPIRTAM	0	0	4	4
SPIRUTAM	0	0	1	1
SPIUTAM	0	0	1	1
SPIVTAM	0	0	1	1
SPLITAM	0	0	1	1
SPRAYTAN	0	1	0	1
SPREE TAM	0	1	0	1
SPREETAM	0	3	0	3
SPREETIEM	0	1	0	1
SPRETAM	0	3	0	3
SPRIETAM	0	1	0	1
SPRINTAM	0	0	1	1
SPRIRTAM	0	0	3	3
SPRITAM	13	4	5	22

SPRITAN	3	0	0	3
SPRUTAM	0	0	1	1
SPURTAM	0	0	2	2

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

No.	Proposed name: Strength(s): 250 mg, 500 mg, 750 mg, 1000 mg (b) (4) Usual Dose: 500 mg po BID; nte 3000mg/day	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	spritam ***	100	Name subject to this review
2.	(b) (4) ***	74	This is a secondary proposed proprietary name, the product was found conditionally acceptable under the name (b) (4) The entire application was withdrawn by the applicant 12/22/2010 (IND (b) (4)).

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.	1,4-SORBitaN	60
2.	Aspartame	56
3.	Citalopram	50
4.	Fluoritab	50
5.	Pentam 300	60
6.	priFTIN	60
7.	Samarium	52
8.	Sani-Foam	54
9.	(b) (4) ***	52
10.	(b) (4) ***	52
11.	Secretin	60
12.	SEROSTIM	58
13.	Serutan	64
14.	SETLAKIN	50
15.	Sinutab	52
16.	Smart San	50
17.	SORBitaN	60

18.	S-Pack DM	52
19.	S-Pak DM	54
20.	Spec-T	50
21.	Spectrum-4	58
22.	Spermidine	50
23.	SPIRIVA	64
24.	sprayzoin	51
25.	spriNTEC	64
26.	spriX	64
27.	Star-Otic	52
28.	Steribath	52
29.	STERI-STAT	57
30.	Steroform	50
31.	STREPTASE	52
32.	STRIANT	60
33.	STRIBILD	52
34.	Stridex	53
35.	Stri-Dex	53
36.	(b) (4)***	60
37.	Strontium	60
38.	Strontium-89	60
39.	Sucrets	53
40.	Sucrets DM	56
41.	SUPPRELIN	50
42.	Supramine	52
43.	SUPRANE	56
44.	SUPRAX	54
45.	Suprep***	50
46.	Suprofen	57
47.	Trital	53
48.	Trital DM	58

49.	Tritan	64
50.	Tussitab	52

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: Spritam** **Strength(s): 250 mg, 500 mg, 750 mg and 1000 mg** (b) (4) **Usual Dose: 250 mg-1500 mg po BID**	**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.	DARApriM	50	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair and the first two syllables sound different.
2.	DIpriVAN	60	Orthographic: The prefixes/infixes have sufficient orthographic differences Phonetic: There are a different number of syllables.
3.	Drituss DM	52	Orthographic: The prefixes and suffixes have sufficient orthographic differences. If the modifier is included it can also be differentiating. Phonetic: The first and second syllables sound different when spoken.
4.	Easprin	52	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: The first and second syllables sound different when spoken.
5.	Fasprin	53	Orthographic: The prefixes/infixes have sufficient orthographic differences. If the modifier is included it can also be differentiating. Phonetic: The first/second syllables sounds different when spoken.
6.	Folitab	52	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair and the first syllable sounds different.
7.	Meperitab	53	Orthographic: The prefixes, infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair and the first three syllables sound different when spoken.

8.	MEpriAM	59	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
9.	PENBritIN	51	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
10.	PENtam	60	Orthographic: The prefixes have sufficient orthographic differences. Phonetic: The first syllable sounds different when spoken.
11.	Piracetam	58	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
12.	priSTIQ	51	Orthographic: The suffixes have sufficient orthographic differences. Phonetic: The second syllable sounds different when spoken.
13.	Procrit	51	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: The first/second syllables sound different when spoken.
14.	Salsitab	51	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
15.	SARAFEM	56	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
16.	SATRIC	50	Orthographic: The infixes have sufficient orthographic differences. Phonetic: The first/second syllables sound different when spoken.
17.	Sloprin	52	Orthographic: The infixes have sufficient orthographic differences. Phonetic: The first/second syllables sound different when spoken.

18.	Solprin	52	Orthographic: The prefixes/infixes have sufficient orthographic differences. Phonetic: The syllables sound different when spoken.
19.	Soprodal	54	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
20.	SORIATANE	53	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
21.	SOTRET	55	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: The first/second syllables sound different when spoken.
22.	(b) (4) ***	52	Orthographic: The prefixes, infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
23.	Spiramycin	52	Orthographic: The infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
24.	Spiretic	62	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
25.	Spirulina	51	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
26.	sprX-105	54	Orthographic: The infixes and suffixes have sufficient orthographic differences. If the modifier is included it can also be differentiating. Phonetic: The syllables sound different when spoken.
27.	sprX-3	54	Orthographic: The infixes and suffixes have sufficient orthographic differences. If the modifier is included it can also be differentiating.

			Phonetic: The syllables sound different when spoken.
28.	sprYCEL	58	Orthographic: The infixes/suffixes have sufficient orthographic differences. Phonetic: The second syllable sound different when spoken.
29.	STERANE	52	Orthographic: The prefixes/infixes have sufficient orthographic differences. Phonetic: The first/second syllables sound different when spoken.
30.	STRATTERA	54	Orthographic: The prefixes, infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
31.	Strazepam	62	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
32.	sumatriptan	50	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
33.	SUPRENZA	54	Orthographic: The infixes and suffixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.
34.	SYpriNE	53	Orthographic: The infixes have sufficient orthographic differences. Phonetic: The syllables sound different when spoken.
35.	VEspriN	52	Orthographic: The prefixes/infixes have sufficient orthographic differences. Phonetic: The syllables sound different when spoken.
36.	dipradam	65	Orthographic: The prefixes and infixes have sufficient orthographic differences. Phonetic: There are different numbers of syllables in the name pair.

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

No.	Name	POCA Score (%)
1.	acetaminophen	28
2.	spectracef	43
3.	spironolactone	36

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
3.	Britiazim	51	International product marketed in UK
4.	Clotam	55	International product marketed in Greece
5.	Dritail	51	Veterinary product
6.	Dysprosium	54	Product is not a drug it is a rare earth element.
7.	Piriton	59	International product marketed in UK, India, Singapore, Hong Kong.
8.	prioderm	54	International product marketed in Belgium, France, Norway, Finland, Sweden, Switzerland, Denmark, Israel
9.	pripsen	54	International product formerly marketed in the UK
10.	pritox	56	Veterinary product
11.	Protamone	52	Name identified in RX Norm database. Unable to find product characteristics in commonly used drug databases.
12.	Sarapin	50	Name identified in RX Norm database. Unable to find product characteristics in commonly used drug databases.
13.	SARENIN	50	International product marketed in Germany
14.	SCOPARIUM	50	International product formerly marketed in Germany and France
15.	(b) (4) ***	50	Name entered by SE. Proposed Proprietary Name found unacceptable by

			DMEPA (OSE# (b) (4)). Product granted proprietary name (b) (4) *** (IND (b) (4))
16.	Sonapram	54	Name identified in RX Norm database. Unable to find product characteristics in commonly used drug databases.
17.	SP RX 228	54	Name identified in RX Norm database. Unable to find product characteristics in commonly used drug databases.
18.	SPARINE	53	International product marketed in UK, Finland, Greece, Ireland, Australia
19.	SPECtamINE	50	discontinued radiologic/diagnostic agent measured in 1mCi/ML; no generics
20.	Spiroctan	64	International product marketed in Brazil and France
21.	Sterillium	52	International product marketed in Sweden, Germany, Ireland, Greece and France
22.	(b) (4) ***	58	This is a secondary proposed proprietary name for this product. Product was approved with the name Sclerosol. (NDA20587).
23.	(b) (4) ***	51	This is a secondary proposed proprietary name for this product. Product was approved with the name DaTscan(NDA022454).
24.	STRIX	56	Discontinued medication with no available generics
25.	Styrene	52	This is not a medication. It is an organic hydrocarbon used to make rubber and plastic.
26.	Suprefact	52	International product

			manufactured in several countries not including the USA
27.	Supreme	60	product is not a drug, it is a glucose blood test
28.	Suramin	52	International product manufactured in Germany.
29.	Surem	50	product is discontinued with no active generics
30.	Surgam	59	International product marketed in several countries not including the USA.
31.	SUritaL	60	Discontinued medication with no available generics.
32.	SuTan-DM	52	Discontinued medication with no available generics.
33.	(b) (4) ***	51	Name identified in Names Entered by SE database. This aplication was withdrawn (BLA (b) (4)) on 12/30/2008 per Darrts
34.	SuTan-DM	53	Discontinued medication with no available generics.

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

No.	Name	POCA Score (%)
1.	82 Strontium	60
2.	85 Strontium	60
3.	Ascriptin	50
4.	Aspergum	52
5.	ASPIRIN	50
6.	Aspirtab	57
7.	Baridium	50
8.	Bridan	59
9.	Brom Tann	52

10.	CAP-PROFEN	50
11.	Cefrom	52
12.	Ceprotin	61
13.	Cerinta	50
14.	Cerium	51
15.	Cipramil	50
16.	Citrical	50
17.	Citroma	50
18.	Clarifoam	50
19.	CROTAN	59
20.	Cuprofen	51
21.	CURATREM	52
22.	CURRETAB	54
23.	Cyprostat	56
24.	Cytogam	52
25.	Difflam	50
26.	DIPENTUM	50
27.	DITROPAN	54
28.	DOPRAM	59
29.	DOPRAM-V	51
30.	Dr.s Cream	56
31.	Dristan	59
32.	droxicam	50
33.	Duratan	58
34.	Duratan DM	50
35.	Epipram	50
36.	EPZICOM	52
37.	ESBRIET	52
38.	ESTRADERM	50
39.	ESTRATAB	63
40.	Estrate	50

41.	Estroplan	50
42.	Estro-Span	50
43.	Estro-Span 40	50
44.	Eye Stream	50
45.	Ferratab	56
46.	Flura-Tab	52
47.	Fortum	52
48.	Frisium	59
49.	hesperetin	50
50.	Hesperidin	51
51.	Larapam	51
52.	Lipram	52
53.	Nitrotan	50
54.	PANRETIN	50
55.	papreeza	52
56.	PAXIPAM	58
57.	Pediatan	52
58.	Perdiem	51
59.	Perestan	54
60.	Perifoam	61
61.	Pet-ema	50
62.	Petrem	53
63.	Phloretin	51
64.	Piroflam	54
65.	Poly Tan	52
66.	Polytan	52
67.	PRANDIN	50
68.	PRANTAL	52
69.	PRAZEPAM	59
70.	Precian	56
71.	Predate-50	51

72.	Predfoam	56
73.	Prefrin	52
74.	PREFRIN-A	50
75.	PRE-PEN	56
76.	Prep-Hem	60
77.	PRE-SATE	51
78.	Pretz	53
79.	Pretz-D	51
80.	PREVIFEM	54
81.	Prevtrom	58
82.	Pro Otic	50
83.	Pro1tek	51
84.	PROCAN	57
85.	Procet	51
86.	PROCOMP	52
87.	Proderm	55
88.	Prodium	59
89.	Prodrin	50
90.	PROFEN	52
91.	Progan	54
92.	Program	60
93.	PROMETA	52
94.	Propa P.H.	50
95.	Propade	50
96.	Propan	60
97.	Propane	54
98.	Pro-Pen-G	50
99.	Propet	52
100.	PROSOM	60
101.	Prostap 3	56
102.	PROSTEP	51

103.	Protac	57
104.	Protid	55
105.	Protopam	61
106.	Protuss DM	52
107.	Pseubrom	50
108.	PURIXAN	52
109.	PYRIDAMAL 100	52
110.	pyridium	57
111.	Pyril DM	52
112.	Pyril Tann-12	54
113.	Q-Profen	55
114.	Re Tann	51
115.	Respigam	56
116.	Respiram	54
117.	Respi-TANN	56
118.	Rimapam	51
119.	Traxam	56
120.	Tretten	51
121.	Triam	55
122.	Triban	54
123.	Tridane	54
124.	TRIDERM	55
125.	Triotann	56
126.	Tropium	50
127.	Viridium	50
128.	Viril Lam	52
129.	Westrim	52
130.	Zopressin	50
131.	Z-Pram	61
132.	Zypram	56

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LOLITA G WHITE
12/12/2014

IRENE Z CHAN
12/12/2014