CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212516Orig1s000

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:	February 7, 2019
Application Type and Number:	NDA 212516
Product Name and Strength:	Drizalma Sprinkle*** (duloxetine) Delayed-release capsules, 20 mg, 30 mg, 40 mg, and 60 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharma Global FZE (Sun Pharma)
Panorama #:	2018-27382905
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
Acting DMEPA Team Leader:	Teresa McMillan, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Drizalma Sprinkle***, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Sun Pharma did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Sun Pharma previously submitted the proposed proprietary name, [redacted] Sprinkle*** on May 18, 2018. However, we found the name, [redacted] Sprinkle*** unacceptable under IND 131008 on October 15, 2018 due to orthographic and/or phonetic similarities and shared product characteristics with the proposed proprietary names [redacted]***, [redacted]***, and [redacted]***.[a]

Thus, Sun Pharma submitted the name, Drizalma Sprinkle***, for review on November 16, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 16, 2018.

- Intended Pronunciation: dri zal' mah
- Active Ingredient: duloxetine
- Indication of Use: Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Diabetic Peripheral Neuropathic Pain (DPNP), Chronic Musculoskeletal Pain (CMP)
- Route of Administration: Oral
- Dosage Form: Delayed-release capsules
- Strength: 20 mg, 30 mg, 40 mg, and 60 mg
- Dose and Frequency:

  Major Depressive Disorder (MDD): Acute Treatment: 40 mg/day (20 mg twice daily) to 60 mg/day (once daily or as 30 mg twice daily); Maintenance Treatment: 60 mg/day

  Generalized Anxiety Disorder (GAD):
  Adults: 60 mg/day (once daily)
  Elderly: 60 mg/day (once daily)
  Children and Adolescents (7 to 17 years of age): 30 to 60 mg/day (once daily)

  Diabetic Peripheral Neuropathic Pain (DPNP), Chronic Musculoskeletal Pain (CMP):
  60 mg/day (once daily)

[a]Holmes L. Proprietary Name Review for Simdeyo Sprinkle (IND 131008). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Oct 15. Panorama No. 2018-22457747.

Maximum Daily Dose (dose in a 24- hour period): 120mg/day for Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD); 60mg/day for Diabetic Peripheral Neuropathic Pain (DPNP), Chronic Musculoskeletal Pain (CMP)

- How Supplied: Bottles of 30, 60, 90, and 1000 capsules
- Storage: Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature.]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Drizalma Sprinkle*** would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Psychiatry Products (DPP) concurred with the findings of OPDP's assessment for Drizalma Sprinkle***.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Drizalma Sprinkle***.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name contains two components: 1) the proposed root name "Drizalma" and 2) the modifier "Sprinkle". Sun Pharma indicated in their submission that the proposed root name "Drizalma" is derived from a blank canvas and the modifier "Sprinkle" means to disperse.

The modifier "Sprinkle", may be misleading since it may imply that the capsule must be sprinkled on food. However, the capsule can be swallowed whole, the contents can be sprinkled over food prior to administration, or the capsule contents can be administered via a nasogastric tube. We note this naming convention has been used for capsules that may be swallowed whole or sprinkled on food (e.g., Topamax Sprinkle, Depakote Sprinkle, and Klor-Con Sprinkle). Because the capsule contents can be sprinkled over food prior to administration, the modifier "Sprinkle" does not present a safety concern. We note that modifiers may be omitted or overlooked; however, in the case for Drizalma Sprinkle***, there is no product marketed under the root name Drizalma that could be dispensed in error. Additionally, since Drizalma Sprinkle*** capsules can be administered by swallowing whole, sprinkling on food, or via nasogastric tube, we do not anticipate that omission of the modifier will result in medication errors of wrong technique in administration. Therefore, we do not object to the use of the modifier "Sprinkle" in this case. We also note that, ultimately, the acceptability of the modifier

[b] USAN stem search conducted on December 23, 2018.

"Sprinkle" will be based on the acceptability of the CMC data to support the method of administration for the product.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 30, 2018 e-mail, the Division of Psychiatry Products (DPP) forwarded the following comments and concerns relating to Drizalma Sprinkle*** at the initial phase of the review:

> *The Division/review team have no concern(s) with the proposed proprietary name (Drizalma Sprinkle). But the OPQ team had the following comments.*
>
> *OPQ Comments: We are sure that DMEPA will look at the 2 or 3 other examples of products with 'sprinkle' in the proprietary name. "Aciphex Sprinkle" are capsules that must be sprinkled, not swallowed whole.*
>
> *This current version of the label directs that this product be swallowed whole (Highlights). Section 2 of the PI also has sprinkling through food as an option for those with difficulty swallowing. The acceptability of this approach is likely still under review by OPQ.*
>
> *Even though, 'sprinkle' is not an official OPQ or USP nomenclature term for nonproprietary names, this would not preclude its general use in proprietary names – once we find this means of administration acceptable.*

2.2.4 FDA Name Simulation Studies

One hundred eight (108) practitioners participated in DMEPA's prescription studies for Drizalma Sprinkle***. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 121 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

[c] POCA search conducted on December 21, 2018 in version 4.3.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	108
Low similarity name pair: combined match percentage score ≤54%	10

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

Our analysis of the 121 names contained in Table 1 determined none of the names will pose a risk for confusion with Drizalma Sprinkle*** 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 Psychiatry Products (DPP) via e-mail on January 30, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry Products (DPP) on February 6, 2019, they stated no additional concerns with the proposed proprietary name, Drizalma Sprinkle***.

3 CONCLUSION

The proposed proprietary name, Drizalma Sprinkle***, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO SUN PHARMA GLOBAL FZE

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

If any of the proposed product characteristics as stated in your submission, received on November 16, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

3. ***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).

4. ***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#).

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

APPENDICES

Appendix A

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

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

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).

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

Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.

- Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail.

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

The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?

Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.

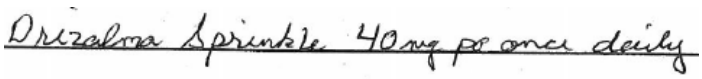
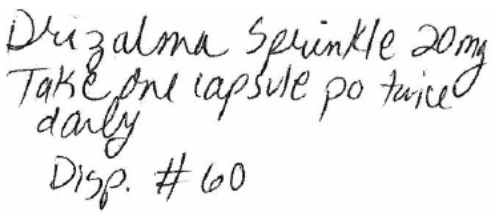
<table>
<tr><td></td><td colspan="2">Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>Orthographic Checklist (Y/N to each question)
Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
Is there different number or placement of cross-stroke or dotted letters present in the names?
Do the infixes of the name appear dissimilar when scripted?
Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
Do the names have different number of syllables?
Do the names have different syllabic stresses?
Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

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

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Drizalma Sprinkle* Study (Conducted on January 4, 2019)**

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Drizalma Sprinkle*** 20 mg Take one capsule by mouth once daily Dispense 60
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

	305 People Received Study
	108 People Responded

Study Name: Drizalma Sprinkle

Total	25	64	19	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DRAMALZA SPRINKLE	0	1	0	1
DRAZALMA SPRINKLE	0	1	0	1
DRAZAMA	0	1	0	1
DRAZOLMA SPRINKLE	0	1	0	1
DRAZOMA	0	1	0	1
DRESALMA SPRINKLE	0	2	0	2
DRESOLMA SPRINKLE	0	2	0	2
DRESOMA	0	1	0	1
DREZALMA	0	1	0	1
DREZALMA SPRINKLE	0	2	0	2

DREZALMA SPRINKLES	0	1	0	1
DRISALMA	0	1	0	1
DRISALMA SPRINKLE	0	4	0	4
DRISELMA SPRINKLE	0	1	0	1
DRISNALMO	0	1	0	1
DRISOLMA	0	1	0	1
DRISOLMA SPRINKLE	0	1	0	1
DRISOMA	0	1	0	1
DRISULMA	0	1	0	1
DRISULMA SPRINKLE	0	1	0	1
DRIZALMA	5	9	3	17
DRIZALMA SPINKLE	0	0	1	1
DRIZALMA SPRINKLE	20	10	14	44
DRIZNOMA	0	1	0	1
DRIZOLAM SPRINKLE	0	0	1	1
DRIZOLMA	0	4	0	4
DRIZOLMA SPRINKLE	0	3	0	3
DRIZOLMA SPRINKLES	0	1	0	1
DRIZOMA SPRINKLE	0	1	0	1
DRIZONAL	0	1	0	1
DRIZULMA	0	1	0	1
DRYSALSA	0	1	0	1
DRYZALMA SPRINKLE	0	2	0	2
TRESALMA	0	1	0	1
TRESOMA SPRINGKLE	0	1	0	1

TRIZOLMA SPRINKLE	0	1	0	1
TRIZOMA	0	1	0	1

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

No.	**Proposed name:** Drizalma Sprinkle*** **Established name:** duloxetine **Dosage form:** Delayed-release capsules **Strengths:** 20 mg, 30 mg, 40 mg, and 60 mg **Usual Dose:** 20 mg to 60 mg orally once or twice daily (depending on the indication). Maximum dose is 120 mg/day.	**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.	Drizalma***	100	This is the root name for Drizalma Sprinkle***, which is the subject of this review.
2.	Drizalma Sprinkle***	52[f]	This name is the subject of this review.
3.	Darcalma	74	Orthographically, the infix letters "riz" vs. "arc" look different. Additionally, when written with a downstroke, the letter "z" further helps to differentiate the name pair. Furthermore, including the Drizalma*** modifier "Sprinkle" when written helps to mitigate potential confusion between the name pair. Phonetically, the first syllables ("Dri" vs. "Dar") sound different. Additionally, the second syllables ("zal" vs. "cal") sound different due to the differences in sound between the letter "z" and the hard "k" sound of the letter "c". Furthermore, including the Drizalma*** modifier "Sprinkle" when spoken helps to mitigate potential confusion between the name pair. Moreover, the products differ in strength [20 mg, 30 mg, 40 mg, and 60 mg vs. single strength, multiple ingredients (81.6 mg methenamine, 36.2 mg phenyl salicylate, 10.8 mg methylene blue,

[f] The root name "Drizalma" was searched in POCA.

No.	**Proposed name:** Drizalma Sprinkle*** **Established name:** duloxetine **Dosage form:** Delayed-release capsules **Strengths:** 20 mg, 30 mg, 40 mg, and 60 mg **Usual Dose:** 20 mg to 60 mg orally once or twice daily (depending on the indication). Maximum dose is 120 mg/day.	**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.**
			40.8 mg sodium phosphate monobasic, 0.12 mg hyoscyamine sulfate)]. Therefore, a prescription for Drizalma Sprinkle would need to indicate the strength whereas a prescription for Darcalma would not which would help mitigate potential confusion between the name pair.
4.	Tricalm	70	Orthographically, the beginning letters of the names look different when written ("D" vs. "T") due to the cross stroke of the letter "T". Additionally, the fourth position letters "z" vs. "c" are further differentiated when the letter "z" is written with a downstroke. Phonetically, the name "Tricalm" contains two syllables whereas the root name "Drizalma" contains three syllables which helps to differentiate the name pair. Furthermore, Tricalm is available in three dosage forms (gel, cream, and spray) that contain different ingredients and/or differ in strength (0.2%, no strength, and 0.3%, respectively). Therefore, if a prescription is written for Tricalm the dosage form would need to be specified which may help to mitigate potential confusion between the name pair. There is no overlap in dosage forms.

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

No.	Name	POCA Score (%)
1.	Darzalex	58

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

No.	**Proposed name:** Drizalma Sprinkle*** **Established name:** duloxetine **Dosage form:** Delayed-release capsules **Strengths:** 20 mg, 30 mg, 40 mg, and 60 mg **Usual Dose:** 20 mg to 60 mg orally once or twice daily (depending on the indication). Maximum dose is 120 mg/day.	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.	Dr. Oh Balm	68	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.
3.	Durvalumab	63	This name pair has sufficient orthographic and phonetic differences.
4.	Dralzine	62	This name pair has sufficient orthographic and phonetic differences.
5.	Seizalam	61	This name pair has sufficient orthographic and phonetic differences.
6.	Uricalm	60	This name pair has sufficient orthographic and phonetic differences.
7.	Diaderm	58	This name pair has sufficient orthographic and phonetic differences.
8.	Durasal	58	This name pair has sufficient orthographic and phonetic differences.
9.	Durasal II	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Drizalma Sprinkle*** **Established name:** duloxetine **Dosage form:** Delayed-release capsules **Strengths:** 20 mg, 30 mg, 40 mg, and 60 mg **Usual Dose:** 20 mg to 60 mg orally once or twice daily (depending on the indication). Maximum dose is 120 mg/day.	**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**
10.	Cuadriderma	57	This name pair has sufficient orthographic and phonetic differences.
11.	Dermasil	57	This name pair has sufficient orthographic and phonetic differences.
12.	Derifil	56	This name pair has sufficient orthographic and phonetic differences.
13.	Diazepam	56	This name pair has sufficient orthographic and phonetic differences.
14.	Diprivan	56	This name pair has sufficient orthographic and phonetic differences.
15.	Dorzolamide	56	This name pair has sufficient orthographic and phonetic differences.
16.	Dramamine	56	This name pair has sufficient orthographic and phonetic differences.
17.	Drisdol	56	This name pair has sufficient orthographic and phonetic differences.
18.	Dristan	56	This name pair has sufficient orthographic and phonetic differences.
19.	Durezol	56	This name pair has sufficient orthographic and phonetic differences.
20.	Durlaza	56	This name pair has sufficient orthographic and phonetic differences.
21.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
22.	Gordobalm	56	This name pair has sufficient orthographic and phonetic differences.
23.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
24.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
25.	Duzallo	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Nizoral A-D	54
2.	(b) (4) ***	52
3.	(b) (4) ***	52
4.	Rimadyl	50
5.	Lariam	50
6.	Dial	49
7.	Giardia Lamblia	48
8.	(b) (4) ***	48
9.	Drize	48

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.	Dritail	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4) ***	61	Proposed proprietary name for NDA (b) (4). The name was withdrawn by the Applicant. The previously proposed name, (b) (4) *** was submitted for reconsideration but a CR action was taken prior to re-review of the name.
3.	Alprazalam	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Drixoral	58	Brand discontinued with no generic equivalents available. NDA 013483 withdrawn FR effective 11/03/2016.
5.	Duradal HD	58	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
6.	Verticalm	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Dialar	56	International product marketed in the United Kingdom.
8.	Dialume	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
9.	Dical-D	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
10.	Diuresal	56	International product formerly marketed in Switzerland.
11.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found conditionally acceptable DMEPA (OSE# (b) (4)) but later denied in a letter dated (b) (4) due to a "train wreck" scenario. No new names have been submitted.
12.	Dralserp	56	Brand discontinued with no other brands or generic equivalents available.
13.	Drixomed	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
14.	Drolban	56	Brand discontinued with no generic equivalents available. NDA 012936 withdrawn FR effective 03/02/1994.
15.	Durabolin	56	Brand discontinued with no generic equivalents available. NDA 011891 withdrawn FR effective 09/07/2018.
16.	Durabolin 50	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
17.	Duracillin A.S.	56	Brand discontinued with no generic equivalents available. ANDA 060093 withdrawn FR effective 01/04/1993.
18.	Duragal-S	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.

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

No.	Name	POCA Score (%)
1.	Triazolam	67
2.	Miraluma	65
3.	Tri-Luma	65
4.	Triam-A	63
5.	Trimal DH	63
6.	Brodalumab	62
7.	Pyridamal 100	62
8.	Trinalin	62
9.	Abrilada***	61
10.	Brevidil M	60
11.	Rezamid	60
12.	Adrenalin	59
13.	Brotizolam	59
14.	Caraderma	59
15.	Trexima	59
16.	Tri-Zel	59
17.	Cardizem LA	58
18.	Modisal LA	58
19.	Ritalin LA	58
20.	Rivelsa***	58
21.	Toradol IM	58
22.	Trazimera***	58
23.	Triderm	58
24.	(b) (4) ***	58
25.	Truxima***	58
26.	Adrucil	57
27.	Britiazim	57
28.	Cardizem	57
29.	Primalev	57
30.	Primalev 300/10	57
31.	Primalev 300/5	57
32.	Primalev 300/7.5	57
33.	Triavil	57
34.	Triavil 2-10	57
35.	Triavil 2-25	57

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

No.	Name	POCA Score (%)
36.	Triavil 4-10	57
37.	Triavil 4-25	57
38.	Triavil 4-50	57
39.	Viril Lam	57
40.	Bravelle	56
41.	(b) (4)***	56
42.	Brilinta	56
43.	Brinzolamide	56
44.	Carisoma	56
45.	Gerimal	56
46.	Inderal LA	56
47.	Inderide LA	56
48.	Inderide LA 120/50	56
49.	Inderide LA 160/50	56
50.	Inderide LA 80/50	56
51.	Midazolam	56
52.	Mindal DM	56
53.	Pred Mild	56
54.	Priadel	56
55.	Probalan	56
56.	Ritalin	56
57.	Tirilazad	56
58.	Brixadi***	55
59.	(b) (4)***	55
60.	Lialda	55
61.	Prezista	55
62.	Prialt	55
63.	Triac Cold	55
64.	Trital SR	55

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/s/

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