CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213876Orig1s000

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 11, 2019
Application Type and Number:	NDA 213876
Product Name and Strength:	Alkindi Sprinkle (hydrocortisone) oral granules, 0.5 mg, 1 mg, 2 mg and 5 mg per capsule
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Diurnal
Panorama #:	2019-36134300
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Alkindi 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. Diurnal submitted an external name study, conducted by [redacted] (b) (4), for this proposed proprietary root name 'Alkindi' that was previously reviewed by DMEPA.

1.1 REGULATORY HISTORY

Diurnal previously submitted the proposed proprietary name, Alkindi*** on May 15, 2019. We found the name, Alkindi*** conditionally acceptable under IND 123322 on October 22, 2019.[a]

Thus, Diurnal submitted the name Alkindi, for re-review under NDA 213876 on November 29, 2019. However, an amendment to the request for proprietary name review was submitted on January 30, 2020 in which the proposed name was changed from Alkindi*** to Alkindi Sprinkle***. We also note that there is a change in dose, from 8 mg/m^2/day to 15 mg/m^2/day to 8 mg/m^2/day to 15 mg/m^2/day, for NDA 213876. All other product characteristics remain the same.

1.2 PRODUCT INFORMATION

The following product information was provided in the proprietary name submission received on November 29, 2019 and January 30, 2020.

- Intended Pronunciation: ael'kindi spr-en-kle
- Active Ingredient: hydrocortisone
- Indication of Use: Replacement therapy in adrenal insufficiency (AI) in infants, children and adolescents (from birth to <17 years)
- Route of Administration: oral; capsules containing granules to be opened and administered directly in patients' mouth. The granules must be given orally and should not be chewed. The capsule shell must not be swallowed, but carefully opened and the content administered. The granules are either poured directly onto the child's tongue, or the granules are poured onto a spoon and placed in the child's mouth. For children who are able to take soft food, the granules may be sprinkled onto a spoonful of cold or room temperature soft food (such as yogurt or fruit puree) and given immediately.
- Dosage Form: oral granules
- Strength: 0.5 mg, 1 mg, 2 mg and 5 mg per capsule
- Dose and Frequency: Dose is individualized according to response of patient and is typically between 8 mg/m^2/day to 15 mg/m^2/day given in 3-4 divided doses.
- How Supplied: 50 count capsules in bottle.

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[a] Griffis, M. Proprietary Name Review for Alkindi (IND 123322). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Oct 22. Panorama No.: 2019-31263736.

- Storage: Stored in original bottle not above 30℃/86°F. Protect from light.
- Reference Product: Cortef; NDA008697

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

This proprietary name is comprised of a root name, 'Alkindi' and the modifier, 'Sprinkle'. Diurnal did not provide a derivation or intended meaning for the proposed proprietary name, Alkindi Sprinkle. As noted above, the root name, Alkindi, was evaluated previously and found acceptable (see Section 1.1). We note that the proposed dose has changed, however, we agree with the findings from our previous review for the root name, Alkindi. We considered the safety implications of using a modifier and whether the use of the modifier 'Sprinkle' is appropriate. The use of the modifier, Sprinkle, is discussed in Section 2.2.6.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 29, 2020 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to Alkindi Sprinkle at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

97 practitioners participated in DMEPA's prescription studies for Alkindi 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. We note 12 participants omitted the modifier 'Sprinkle' in their responses (see Section 2.2.6). Appendix B contains the results from the verbal and written prescription studies.

[b] USAN stem search conducted on December 13, 2019.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 90 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated all of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We also evaluated previously identified names taking into account the change in dose and addition of the modifier 'Sprinkle'. Our evaluation has not altered our previous conclusion and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified no names that were not previously analyzed.

2.2.6 Safety Analysis of the Proposed Modifier

Alkindi Sprinkle is a multi-particulate granule formulation stored in hard capsules as the storage medium and the capsule itself is not intended for consumption. The proposed product labeling instructs patients/caregivers to open the capsule and sprinkle the granules either directly onto the child's tongue, or the granules are poured onto a spoon and placed in the child's mouth. The granules can also be sprinkled onto a spoonful of cold or room temperature soft food (such as yogurt or fruit puree). The risks associated with users swallowing the capsule whole as well as a potential safety issue of choking since this product is intended for pediatric use will be addressed within the product labels and labeling review.

We considered whether the modifier 'Sprinkle' may be misleading, we note that this naming convention has been used for capsules that may be sprinkled on food (e.g., Topamax Sprinkle,[d] Depakote Sprinkles, and Klor-Con Sprinkle). Thus, because the capsule contents can be sprinkled over food prior to administration, we determined the modifier 'Sprinkle' is not misleading. We acknowledge that omission and oversight of a modifier is cited in literature[e] as a common cause of medication error and we note 12 participants omitted the modifier 'Sprinkle' in FDAs Name Simulation Studies (see Section 2.2.4) however, in the case for Alkindi Sprinkle, there is no product marketed under the root name Alkindi that could be dispensed in error. 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 'Sprinkle' will be based on the acceptability of the CMC data to support the method of administration for the product.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on February 6, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on February 11, 2020, they stated no additional concerns with the proposed proprietary name, Alkindi Sprinkle.

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[c] POCA search conducted on December 13, 2019 in version 4.3.

[d] Formulation discontinued and currently marketed as Topamax sprinkle capsule (NDA 020844).

[e] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

3 CONCLUSION

The proposed proprietary name, Alkindi Sprinkle, is acceptable.

If you have further questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO DIURNAL

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

If any of the proposed product characteristics as stated in your submission, received on November 29, 2019 and January 30, 2020 are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

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

- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. 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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

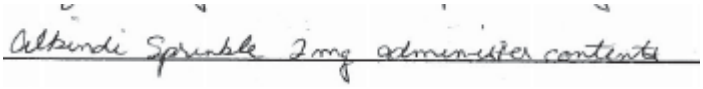
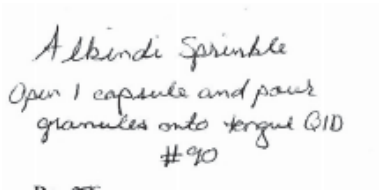
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Alkindi Sprinkle Study (Conducted on January 10, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Alkindi Sprinkle 0.5 mg Open 1 capsule and pour granules onto tongue QID #90
Outpatient Prescription:  	
CPOE Study Sample (Font: sans-serif, 12 point, bold)	
Alkindi Sprinkle	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Alkindi Sprinkle

As of Date 1/27/2020

211 People Received Study

97 People Responded

Study Name: Alkindi Sprinkle

Total	19	21	19	38	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
AILBINDI SPRINKEL	0	0	0	1	1
ALBIND SPRINKLE	0	0	0	1	1
ALBINDI	0	0	0	4	4

ALBINDI SPRINKLE	2	0	0	4	6
ALBUNDI SPRINKLE	0	0	0	2	2
ALKENDI SPRINKLE	0	0	3	0	3
ALKINDEE SPRINKLE	0	0	1	0	1
ALKINDI	0	0	0	5	5
ALKINDI SPRINBLE	1	0	0	0	1
ALKINDI SPRINKEL	0	0	0	1	1
ALKINDI SPRINKLE	16	21	3	14	54
ALKINDI SPRINKLES	0	0	1	0	1
ALKINDIE SPRINKLE	0	0	0	1	1
ALKINDY	0	0	0	1	1
ALKINDY SPRINKLE	0	0	2	0	2
ALKINI SPRINKLES	0	0	0	1	1
ALKUNDI	0	0	0	1	1
ALKYNDI SPRINKLE	0	0	1	0	1
ALQINDI SPRINKLE	0	0	1	0	1
ALQUENDI SPRINKLE	0	0	1	0	1
ARLBINDI	0	0	0	1	1
CULBINDI SPRINKLE	0	0	0	1	1
ELKINDI SPRINKLE	0	0	1	0	1
HALKINDI SPRINKLE	0	0	4	0	4
HELKINDI SPRINKLE	0	0	1	0	1

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

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

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

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

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

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[h].-N/A

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

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/s/

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