CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208042Orig1s000

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)

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Date of This Review:	June 28, 2018
Application Type and Number:	NDA 208042
Product Name and Strength:	Cassipa (Buprenorphine and Naloxone) Sublingual Film 16 mg/4 mg
Product Type:	Multi-Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Teva Pharmaceuticals
Panorama #:	2018-22457813
DMEPA Safety Evaluator:	James Schlick, MBA, RPh
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Cassipa, 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 proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 18, 2018.

- Intended Pronunciation: *CAS-Si-PAh*
- Active Ingredient: buprenorphine and naloxone
- Indication of Use: Maintenance treatment of opioid addiction
- Route of Administration: Sublingual
- Dosage Form: Sublingual Film
- Strength: 16 mg/4mg
- Dose and Frequency: One film under the tongue once daily
- How Supplied: One film per pouch; 30 pouches per carton
- Storage: Room temperature

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[a] USAN stem search conducted on May 2, 2018.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 2, 2018 e-mail, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Forty 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. 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[b] identified 79 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, FDA Prescription Simulation Study, and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	76
Low similarity name pair: combined match percentage score ≤54%	158

[b] POCA search conducted on April 25, 2018 in version 4.2.

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

Our analysis of the 235 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on June 20, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on June 28, 2018 they stated no additional concerns with the proposed proprietary name, Cassipa.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on April 18, 2018, 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 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. [c]

[c] 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[d]. 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.

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

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.

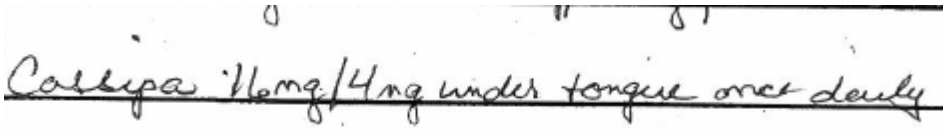
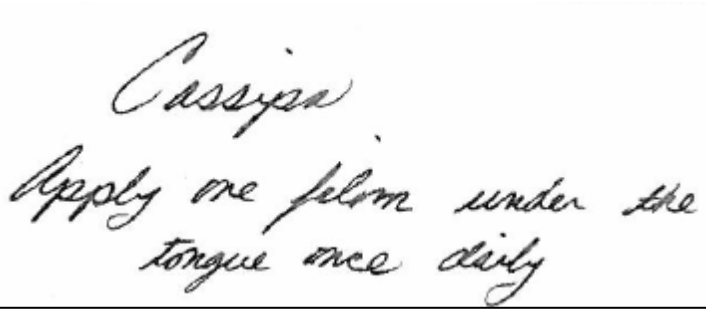
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Cassipa Study (Conducted on May 4, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Cassipa Apply one film under the tongue once daily
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

310 People Received Study
40 People Responded

Study Name: Cassipa

Total	16	9	15	40

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CASIPA	0	3	0	3
CASSIPA	15	2	11	28
CASSIPS	1	0	0	1
COSSIPA	0	0	4	4
KASIPA	0	2	0	2
KASIPPA	0	2	0	2

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

No.	Proposed name: Cassipa Established name: Buprenorphine and Naloxone Dosage form: Sublingual Film Strength(s): 16 mg/4 mg Usual Dose: Apply one film under the tongue once daily	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.	Vascepa	72	The names begin with different letters ('C' vs. 'V') The first syllables have sufficient phonetic differences. Vascepa has multiple strengths (0.5 gm and 1 gm) that do not overlap or are similar to the Cassipa strength. The usual dose of Vascepa is 2 grams (2 or 4 capsules) where the usual dose of Cassipa is 1 film. Thus, there is no overlap or similarity in dose.

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 (%)
2.	Capsin	68
3.	Dasetta 1/35	64
4.	Dasetta 7/7/7	64
5.	(b) (4) ***	61
6.	Sensipar	61
7.	Catapres	56
8.	Caprelsa	55

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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: Cassipa** **Established name: Buprenorphine and Naloxone** **Dosage form: Sublingual Film** **Strength(s): 16 mg/4 mg** **Usual Dose: Apply one film under the tongue once daily.**	**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**
9.	Canasa	66	This name pair has sufficient orthographic and phonetic differences.
10.	Disipal	66	This name pair has sufficient orthographic and phonetic differences.
11.	Incassia	66	This name pair has sufficient orthographic and phonetic differences.
12.	Cafcit	64	This name pair has sufficient orthographic and phonetic differences.
13.	Glassia	64	This name pair has sufficient orthographic and phonetic differences.
14.	Co-Apap	63	This name pair has sufficient orthographic and phonetic differences.
15.	Cancidas	62	This name pair has sufficient orthographic and phonetic differences.
16.	(b) (4) ***	62	This name pair has sufficient orthographic and phonetic differences.
17.	A-Spas	61	This name pair has sufficient orthographic and phonetic differences.
18.	Calcid	60	This name pair has sufficient orthographic and phonetic differences.
19.	Calcitab	60	This name pair has sufficient orthographic and phonetic differences.
20.	Tussitab	60	This name pair has sufficient orthographic and phonetic differences.
21.	Cal Stat	59	This name pair has sufficient orthographic and phonetic differences.
22.	Capacet	58	This name pair has sufficient orthographic and phonetic differences.
23.	Capastat	58	This name pair has sufficient orthographic and phonetic differences.
24.	Capsaicin	58	This name pair has sufficient orthographic and phonetic differences.

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No.	Proposed name: Cassipa Established name: Buprenorphine and Naloxone Dosage form: Sublingual Film Strength(s): 16 mg/4 mg Usual Dose: Apply one film under the tongue once daily.	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
25.	Crysvita	58	This name pair has sufficient orthographic and phonetic differences.
26.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
27.	Oncaspar	58	This name pair has sufficient orthographic and phonetic differences.
28.	Tussin Pe	58	This name pair has sufficient orthographic and phonetic differences.
29.	Silapap	57	This name pair has sufficient orthographic and phonetic differences.
30.	T-Tussin Pe	57	This name pair has sufficient orthographic and phonetic differences.
31.	Tussicaps	57	This name pair has sufficient orthographic and phonetic differences.
32.	Aktipak	56	This name pair has sufficient orthographic and phonetic differences.
33.	Calcet	56	This name pair has sufficient orthographic and phonetic differences.
34.	Calcimar	56	This name pair has sufficient orthographic and phonetic differences.
35.	Capzasin-P	56	This name pair has sufficient orthographic and phonetic differences.
36.	Carospir	56	The infixes ('ssi' vs 'ros') of this name pair have sufficient orthographic differences. This name pair has sufficient phonetic differences.
37.	Cosamin	56	This name pair has sufficient orthographic and phonetic differences.
38.	Cosopt	56	This name pair has sufficient orthographic and phonetic differences.
39.	Capzasin-Hp	50	This name pair has sufficient orthographic and phonetic differences.
40.	Cocet	50	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
41.	Anaspaz	54
42.	Arcapta	54
43.	A-Spas S/L	54
44.	Atopica	54
45.	Atosiban	54
46.	Avita	54
47.	Bicitra	54
48.	C Tussin	54
49.	Cafgesic	54
50.	Calcipine	54
51.	Calimal	54
52.	Calphosan	54
53.	Cambia	54
54.	Camila	54
55.	Capex	54
56.	Caprin	54
57.	Chitosan	54
58.	Claris	54
59.	Close Up	54
60.	Conzip	54
61.	Crysti-12	54
62.	Hespan	54
63.	Kao-Spen	54
64.	Kasof	54
65.	Lessina-21	54
66.	Lessina-28	54
67.	Ocaliva	54
68.	Palipase	54
69.	Sansac	54
70.	Sedapap	54
71.	Supac	54
72.	Sustac	54
73.	Tasmar	54
74.	Tuss Da	54
75.	Aceta	53
76.	Bucalsep	53
77.	Calsynar	53
78.	Caseinate	53
79.	Catechin	53
80.	Child Apap	53

No.	Name	POCA Score (%)
81.	Cuvposa	53
82.	Kalliga	53
83.	Ka-Pec	53
84.	M-Caps	53
85.	Parcopa	53
86.	Q-Tussin Pe	53
87.	Respa	53
88.	4 Face Up	52
89.	5 Face Up	52
90.	Antispas	52
91.	Asepxia	52
92.	Buspar	52
93.	Campto	52
94.	Capoten	52
95.	Carbidopa	52
96.	Cea Scan	52
97.	Claripel	52
98.	Cresatin	52
99.	Cresemba	52
100.	Decaspray	52
101.	Face Up	52
102.	Face Up #2	52
103.	Face Up #3	52
104.	Fastin	52
105.	Glatopa	52
106.	Guaispan	52
107.	Maxepa	52
108.	Nasabid	52
109.	Nasatab	52
110.	Nasin	52
111.	Nasopen	52
112.	Pentasa	52
113.	Pepcid Ac	52
114.	Picato	52
115.	Refissa	52
116.	Rispas	52
117.	Sani-Supp	52
118.	Saphris	52
119.	Savaysa	52
120.	Sinupan	52
121.	Tavist	52
122.	Tavist-1	52
123.	Taztia	52

No.	Name	POCA Score (%)
124.	Tisept	52
125.	Tuss Tan	52
126.	Tussi Press	52
127.	Tussi-12D	52
128.	Tusstat	52
129.	Uticap	52
130.	Calcicard	51
131.	Campath	51
132.	Carlesta	51
133.	Co-Tussin	51
134.	Cyclessa	51
135.	Cystospaz	51
136.	Eucrisa	51
137.	Fansidar	51
138.	Hiserpia	51
139.	Potaba	51
140.	Profasi	51
141.	Scalp-Aid	51
142.	Vanspar	51
143.	Wakespan	51
144.	Aclacin	50
145.	Actacin	50
146.	Amipak	50
147.	Asacol	50
148.	Atripla	50
149.	Bacid	50
150.	Bicarsim	50
151.	Calci-Chew	50
152.	Calcidol	50
153.	Calcilat	50
154.	Calcitare	50
155.	Calcium 600	50
156.	Calpol	50
157.	Capitrol	50
158.	Carac	50
159.	Cardiacap	50
160.	Cayston	50
161.	Cepastat	50
162.	Child Silapap	50
163.	Clarispray	50
164.	C-Tanna 12	50
165.	Despec	50
166.	Diastat	50

No.	Name	POCA Score (%)
167.	D-S Caps	50
168.	Fasprin	50
169.	Gazyva	50
170.	Kitabis	50
171.	Masanti	50
172.	Nasopro 24	50
173.	Ocusan	50
174.	Palcaps	50
175.	Parsabiv	50
176.	Pc-Cap	50
177.	Pet-Ema	50
178.	Piptal	50
179.	Potiga	50
180.	Pp-Cap	50
181.	Rezipas	50
182.	Rt Capsin	50
183.	Salitop	50
184.	Satric	50
185.	Septra	50
186.	Sleepia	50
187.	Tavist Da	50
188.	Testa Span	50
189.	Trasicor	50
190.	Tussafin	50
191.	Tusscidin	50
192.	Tussi-Bid	50
193.	Aspircaf	50
194.	Vasad	50
195.	Vitapap	50
196.	Z Tuss Ac	50

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
197.	C20-40 Acid	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
198.	Capstar	62	Veterinary product.
199.	Captan	62	Product is not a drug. It is a phthalimide fungicide used for agricultural purposes.
200.	Sensipak	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
201.	Cartia	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
202.	caseins	60	Product is not a drug. It is a protein used in allergen extract tests
203.	Catosal	60	Veterinary product.
204.	(b) (4)***	60	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name (NDA 210428).
205.	Cotab A	60	This product is discontinued and no generic equivalents are available.
206.	Paxipam	59	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
207.	(b) (4)***	58	Proposed proprietary name for NDA (b) (4) and IND (b) (4) withdrawn by Applicant. The name, (b) (4), was found acceptable in OSE Review # (b) (4) under IND (b) (4).
208.	Asepso	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
209.	Cam-Ap-Es	56	Name identified in Drugs At FDA database. Product is deactivated (per Drugs at FDA) and no generic equivalents are available.
210.	Carisoma	56	International product for carisoprodol marketed in India.

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

No.	Name	POCA Score (%)
211.	Pacis	64
212.	Dispas	62
213.	Tasigna	60
214.	Basis	58
215.	Pacaps	58
216.	Samsca	58
217.	Tresiba	58
218.	Apacet	57
219.	Pepsin A	57
220.	Qsymia	57
221.	Acitak 200	56
222.	Acitak 400	56
223.	Acitak 800	56
224.	(b) (4)***	56
225.	Fiasp	56
226.	Fiv-Asa	56
227.	Nasop	56
228.	Nesina	56
229.	Niaspan	56
230.	Q-Acin	56
231.	Salsitab	56
232.	(b) (4)***	55
233.	Kariva	55
234.	Septa	55
235.	Sustiva	55

[e] 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/

JAMES H SCHLICK
06/28/2018

OTTO L TOWNSEND
06/29/2018