CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216632Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Review:	March 22, 2023
Application Type and Number:	NDA 216632
Product Name and Strength:	Cabtreo (clindamycin phosphate/adapalene/benzoyl peroxide) topical gel, 1.2% / 0.15% / 3.1%
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bausch Health US, LLC (Bausch)
PNR ID #:	2022-1044724909
DMEPA 1 Safety Evaluator:	Corwin D. Howard, PharmD, RPh
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Cabtreo, 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. Bausch 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 December 22, 2022.

- Intended Pronunciation: kab-TREE-oh
- Active Ingredient: clindamycin phosphate/adapalene/benzoyl peroxide
- Indication of Use: treatment of acne vulgaris in patients (b) (4) years of age and older.
- Route of Administration: topical
- Dosage Form: topical gel
- Strength: 1.2% / 0.15% / 3.1%
- Dose and Frequency: Apply a thin layer of to the affected areas once daily.
  - Avoid the eyes, mouth, paranasal creases, and mucous membranes.
  - Not for oral, ophthalmic, or intravaginal use.
- How Supplied: 20 g tube, 50 g tube, 20 g pump, 50 g pump
- Storage: Prior to Dispensing: store in a refrigerator, 2° to 8°C (36° to 46°F).. Once dispensed, store at room temperature at or below 25°C (77°F).
- Reference Listed Drug/Reference Product: "Epiduo Forte" NDA 207917

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Cabtreo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Cabtreo. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Cabtreo.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Bausch indicated in their submission that the proposed proprietary name, Cabtreo, is "derived from the first three letters 'c', 'a', and 'b' of the product's active ingredients: clindamycin phosphate, adapalene and benzoyl peroxide, and reference to these 3 ingredients as 'treo'; a variant of the word 'trio' that implies a group of three, in this case the three active ingredients." This proprietary name is comprised of a single word. We note that Cabtreo contains the letter string: '-tr-' an abbreviation used for 'time release'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that due to the location of this abbreviations in the middle of the name and its lack of prominence, it is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we conclude that in this case, the letter string '-tr-' in the name is acceptable.

Beyond this abbreviation, we note that Cabtreo does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 19, 2023, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Cabtreo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-six (n=86) practitioners participated in DMEPA's prescription studies for Cabtreo. 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 prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 115 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 Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

[a] USAN stem search conducted on December 28, 2022.

[b] POCA search conducted on December 28, 2022 in version 5.1.

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	87
Low similarity name pair: combined match percentage score ≤54%	28

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

Our analysis of the 117 names contained in Table 1 determined none of the names will pose a risk for confusion with Cabtreo as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On March 22, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Cabtreo, is conditionally acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO BAUSCH HEALTH US, LLC

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

If any of the proposed product characteristics as stated in your submission, received on December 22, 2022, 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. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***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

[d] 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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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.

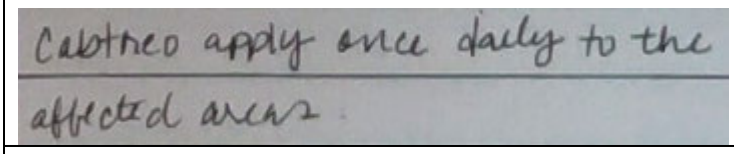
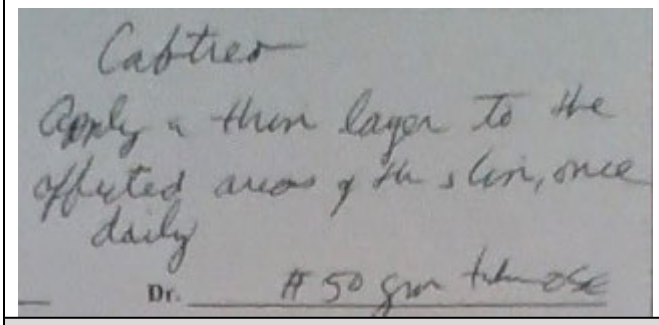
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Cabtreo Study (Conducted on January 6, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Cabtreo	Cabtreo Apply a thin layer to the affected areas of the skin once daily 50 g

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Cabtreo

As of Date 3/9/2023

258 People Received Study
86 People Responded

Study Name: Cabtreo

Total	24	23	21	18	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
CAB TRIO	0	0	1	0	1
CABSTREO	1	0	0	0	1
CABTOREO	2	0	0	0	2
CABTREO	18	23	1	17	58
CABTRIO	0	0	10	0	9
CAFTREO	0	0	0	1	1
CALSTREO	3	0	0	0	3

CAPTRIO	0	0	2	0	2
KABTRIO	0	0	2	0	2
KAPTREO	0	0	1	0	1
KEPTRIO	0	0	1	0	1
TABTREO	0	0	1	0	1
TABTRIO	0	0	2	0	2

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

No.	**Proposed name:** Cabtreo **Established name:** clindamycin phosphate/adapalene/benzoyl peroxide **Dosage form:** topical gel **Strength(s):** 1.2% / 0.15% / 3.1% **Usual Dose:** Apply a thin layer to the affected areas of the skin 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.	Cabtreo***	100	Subject of this review
2.	Caltro	72	The letter 'e' in the 6th position of Cabtreo, not present in Caltro, provides some orthographic difference. Cabtreo name contains an extra syllable. The ending sounds of the first syllables ('b' vs. 'l') and the second syllables (TREE vs. tro) provide some phonetic differences. Additionally, the products differ in dosage form (topical gel vs. tablet) and route of administration (topically vs. oral); these product characteristic differences provide additional differentiation if included on a prescription. Furthermore, we note that the drug product was not found in most of the commonly used databases, including Drugs@FDA and Orange Book and Caltro is listed as 'deactivated' since December 1997 per Redbook.

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.	Carbatrol	68
2.	Caltrate	65
3.	(b) (4)***	62
4.	Tabrecta	60

No.	Name	POCA Score (%)
5.	Breo	56
6.	Crestor	56
7.	Capoten	55

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:** Cabtreo **Established name:** clindamycin phosphate/adapalene/benzoyl peroxide **Dosage form:** topical gel **Strength(s):** 1.2% / 0.15% / 3.1% **Usual Dose:** Apply a thin layer to the affected areas of the skin 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**
1.	Contrave	64	This name pair has sufficient orthographic and phonetic differences.
2.	Catapres	63	This name pair has sufficient orthographic and phonetic differences.
3.	Pimtrea	63	This name pair has sufficient orthographic and phonetic differences.
4.	Cafetrate	63	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences
6.	Altreno	61	This name pair has sufficient orthographic and phonetic differences
7.	Compro	61	This name pair has sufficient orthographic and phonetic differences
8.	Recarbrio	60	This name pair has sufficient orthographic and phonetic differences
9.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
10.	Campral	58	This name pair has sufficient orthographic and phonetic differences.
11.	Castor Oil	58	This name pair has sufficient orthographic and phonetic differences
12.	(b) (4)***	58	This name pair has sufficient orthographic and phonetic differences.
13.	Carboprost	57	This name pair has sufficient orthographic and phonetic differences

No.	**Proposed name:** Cabtreo **Established name:** clindamycin phosphate/adapalene/benzoyl peroxide **Dosage form:** topical gel **Strength(s):** 1.2% / 0.15% / 3.1% **Usual Dose:** Apply a thin layer to the affected areas of the skin 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**
14.	Jetrea	57	This name pair has sufficient orthographic and phonetic differences
15.	Vocabria	57	This name pair has sufficient orthographic and phonetic differences
16.	Coal Tar	56	This name pair has sufficient orthographic and phonetic differences
17.	Calcitrol	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.	B-Caro-T	54
2.	Carbodec Tr	54
3.	Cocoa Butter	54
4.	Carbacot	54
5.	Carbatab 12	54
6.	Carbomer	54
7.	Carbomer 1342	54
8.	Carbomer-934	54
9.	Carbomer-940	54
10.	Carbomer-980	54
11.	Trecator	52
12.	Canrenoate	52
13.	Carbodec	52
14.	Cabotegravir	52
15.	Carteolol	51
16.	Coartem	51
17.	Carbonate Ion	50
18.	Bock-Arate	50
19.	Octreoscan	48
20.	Orabrite	48
21.	Oto Care	46
22.	Ecocare	46

No.	Name	POCA Score (%)
23.	Ecocare 250	46
24.	Ecocare 350	46
25.	Ecocare 370	46
26.	Acarbose	45
27.	Otic Care	44
28.	Cabometyx	42

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.	Cartrol	68	Brand discontinued with no generic equivalents available. NDA 019204 withdrawn FR effective 7/8/2011.
2.	Cebatrol	67	International product market in Canada
3.	(b) (4)***	66	Proposed proprietary name (b) (4)
4.	Capitrol	64	Brand discontinued with no generic equivalents available. Withdrawn Pending FR Notice 7/20/2007 (NDA 17594).
5.	(b) (4)***	63	Proposed proprietary name (b) (4)
6.	Kemstro	62	Brand discontinued with no generic available. NDA 021589 withdrawn FR effective 7/21/2017.
7.	Natrecor	60	Brand discontinued with no generic equivalents available. NDA 020920 withdrawn FR effective 06/15/2020.
8.	Catarase	60	Brand discontinued with no generic equivalent available.
9.	Capstar	59	Veterinary product.
10.	Factrel	59	Veterinary product.
11.	(b) (4)***	58	Proposed proprietary name for NDA 210136 found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). NDA 210136 was tentatively approved under the proprietary name, Brixadi***.
12.	Campto	58	International product marketed in various countries outside of the U.S.

No.	Name	POCA Score (%)	Failure preventions
13.	Kantrex	58	Brand discontinued with no generic equivalents available. ANDAs 060516 (withdrawn FR effective; 4/05/1993), 061655 (withdrawn FR effective; 08/05/2003), 061901 (withdrawn FR effective; 08/19/2013), 061911 (withdrawn FR effective; 04/05/1994), 062564 (withdraw FR effective; 04/29/1994), and 062726 (withdrawn FR effective; 03/09/2004).
14.	Cardec Tr	57	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
15.	Citrate	57	Product is not a drug. It is derivative of citric acid not available as a stand-alone product.
16.	Carbiset Tr	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
17.	Calabren	56	International product formerly marketed in the UK and Hong Kong.
18.	Curatrem	56	Veterinary drug product.
19.	Cantharone	56	Discontinued cantharidin product with no generic equivalents available.
20.	Cardrase	56	Brand discontinued with no generic equivalents available. NDA 011047 withdrawn FR effective 3/02/1994.
21.	Carifree	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Centrine	56	Veterinary product.
23.	(b) (4) ***	56	Proposed proprietary name, (b) (4) *** was found conditionally acceptable by DMEPA under IND 132547 (OSE#: 2018-23376042 dated August 7, 2018). However, this product was approved with a different proprietary name, Trikafta, under NDA 212273.
24.	Raphtre	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	(b) (4) ***	52	Proposed proprietary name for NDA 208945 found unacceptable by DMEPA (OSE# 2016-9412542). NDA 208945 approved under the proprietary name Xepi.
26.	Coracten	49	International drug product marketed in Hong Kong and United Kingdom. International drug product formerly marketed in Thailand and Germany.

No.	Name	POCA Score (%)	Failure preventions
27.	Bravecto	48	Veterinary product.
28.	Ascorbate	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Ascorbate is also the anion of ascorbic acid.
29.	Procaterol	48	International product marketed in Japan, China, Indonesia, and Philippines.
30.	Nicabate	47	International product marketed in Australia, New Zealand and the UK.
31.	Cocoate	46	Product is not a drug. It is a resulting compound derived from coconut oil.

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 (%)
1.	Econtra	64
2.	Kcentra	62
3.	Gavreto	61
4.	Testro	61
5.	Habitrol	60
6.	Tartrate	60
7.	Pedtrace-4	59
8.	(b) (4) ***	58
9.	Odactra	58
10.	Tab-Profen	58
11.	Tact Cream	58
12.	Actron	56
13.	Femtrace	56
14.	Gabitril	56
15.	Kaletra	56
16.	Natroba	56
17.	Septra	56
18.	Tabradol	56
19.	Tempra	56
20.	Tempra 1	56
21.	Tempra 2	56

[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

No.	Name	POCA Score (%)
22.	Tempra 3	56
23.	Testro Aq	56
24.	Testro-L.A.	56
25.	Abstral	55
26.	Bextra	55
27.	Estro-A	55
28.	E-Z-Cat Dry	55
29.	Kalbitor	55
30.	Magtrate	55
31.	Seb-Prev	55
32.	Tetracon	55

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/s/

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