

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217927Orig1s000

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)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 20, 2023
Application Type and Number:	NDA 217927
Product Name and Strength:	Coxanto (oxaprozin) capsule, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Solubiomix, LLC. (Solubiomix)
PNR ID #:	2022-1044724908
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Coxanto, 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. Solubiomix did not submit an external name study 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: kox an' toe
- Active Ingredient: oxaprozin
- Indication of Use: Relief of the signs and symptoms of:
 - Osteoarthritis (OA)
 - Rheumatoid arthritis (RA)
 - Juvenile rheumatoid arthritis (JRA)
- Route of Administration: oral
- Dosage Form: capsule
- Strength: 300 mg
- Dose and Frequency:
 - OA and RA: 1,200 mg (four 300 mg capsules) given orally once a day
 - JRA:

Body Weight Range (kg)	Dose (mg)
22 kg - 31kg	600 mg (2 capsules)
32 kg - 54 kg	900 mg (3 capsules)
≥55 kg	1,200 mg (4 capsules)

- How Supplied: Bottles of 60 capsules
- Storage: Store at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- Reference Listed Drug: Daypro (NDA 018841)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Coxanto 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 Coxanto. The Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Coxanto.

2.2 SAFETY ASSESSMENT

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

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

Solubiomix indicated in their submission that the proposed proprietary name, Coxanto, links to the mechanism of action, COX inhibition. 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 can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On February 9, 2023, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Coxanto at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (n=90) practitioners participated in DMEPA's prescription studies for Coxanto. One participant in the Computerized Physician Order Entry (CPOE) study selected the proprietary name Coversyl instead of Coxanto, which is a direct hit to the international product Coversyl. We note that the participant did not enter any letters into the search bar during the CPOE study. Subsequently, the participant was presented with a static list of names, where Coxanto appeared as the third name below Coversyl. We note that the participant took significantly longer to select a name from the static pick list compared to the amount of time taken to select remaining study names that were included in the CPOE study (36 seconds for Coxanto *versus* 5 to 11 seconds per each other name). Thus, it appears the participant selected an answer closest to the response needed given the goal of the simulated study. Given Coversyl is an international product not marketed in the U.S., we find the risk of name confusion is minimized (see Appendix G).

The remaining 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.

^a USAN stem search conducted on December 28, 2022.

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search^b identified 111 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. 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 and FDA Prescription Simulation 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	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	108
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 112 names contained in Table 1 determined none of the names will pose a risk for confusion with Coxanto as described in Appendices C through H.

2.2.8 *Communication of DMEPA's Determination*

On March 20, 2023, DMEPA 1 communicated our determination to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP).

3 CONCLUSION

The proposed proprietary name, Coxanto, is conditionally acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

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

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

***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)).

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

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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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.

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,

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

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 $\geq 70\%$).

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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	Y/N	Do the syllables have different phonologic processes, such

	upstroke/downstroke letters present in the names?		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 $\geq 55\%$ to $\leq 69\%$)

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 <u>with</u> overlapping or similar strengths or doses.

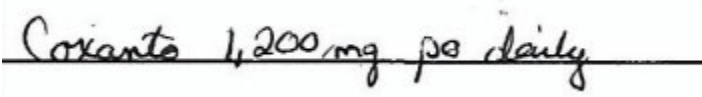
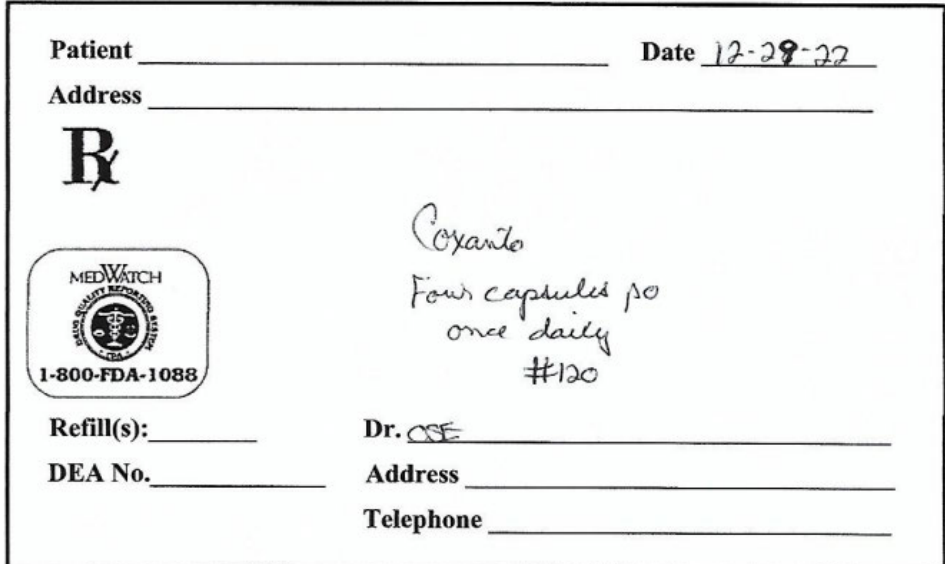
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Coxanto Study (Conducted on December 29, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Coxanto Take four capsules by mouth once daily
Outpatient Prescription: 	#120
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Coxanto	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Coxanto					
259 People Received Study					
90 People Responded					
Study Date: December 29, 2022					
Total	22	25	19	24	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
COCSANTO	0	0	1	0	1
COCSENTO	0	0	1	0	1
COVERSYL	0	1	0	0	1
COXANTE	1	0	0	0	1
COXANTO	21	24	4	24	73
COXSANTO	0	0	5	0	5
KOCSANTO	0	0	1	0	1
KOKSANTO	0	0	1	0	1
KOXANTO	0	0	1	0	1
PAXANTO	0	0	1	0	1
TAXANTO	0	0	1	0	1
TOKSANTO	0	0	1	0	1
TOXANTO	0	0	1	0	1
TOXCENTO	0	0	1	0	1

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

No.	Proposed name: Coxanto Established name: oxaprozin Dosage form: capsule Strength(s): 300 mg Usual Dose: 600 mg (2 capsules) to 1,200 mg (4 capsules) 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.	Coxanto	100	This name is the subject of this review.
2.	Oxantel	72	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	(b) (4)	72	(b) (4)

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

No.	Name	POCA Score (%)
1.	Concerta	64
2.	Concept Ob	63

No.	Name	POCA Score (%)
3.	(b) (4) ***	62
4.	Dixlanta	62
5.	Roxanol	62
6.	Roxanol-T	62
7.	Comtan	60
8.	Tascenso	60
9.	Calfactant	58
10.	Chitosan	58
11.	Cinvanti	58
12.	Cleocin T	58
13.	Cleocin-T	58
14.	Conate	58
15.	Conceptrol	58
16.	Contac Cold	58
17.	Conte-Pak-4	58
18.	Copaxone	58
19.	Cortane-B	58
20.	Cotacort	58
21.	Crotamiton	58
22.	Crotan	58
23.	Dexilant	58
24.	Duoplant	58
25.	Mitoxantrone	58
26.	Oxandrin	58
27.	Proxacol	58
28.	Xaciato	58

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

No.	Proposed name: Coxanto Established name: oxaprozin Dosage form: capsule Strength(s): 300 mg Usual Dose: 600 mg (1 capsule) to 1,200 mg (4 capsules) 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.	Cytoxan	68	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.
3.	Ciloxan	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Coxanto Established name: oxaprozin Dosage form: capsule Strength(s): 300 mg Usual Dose: 600 mg (1 capsule) to 1,200 mg (4 capsules) 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
4.	Carnitor	58	This name pair has sufficient orthographic and phonetic differences.
5.	Cogentin	58	This name pair has sufficient orthographic and phonetic differences.
6.	Congestant	58	This name pair has sufficient orthographic and phonetic differences.
7.	Cortan	58	This name pair has sufficient orthographic and phonetic differences.
8.	Cosamin	58	This name pair has sufficient orthographic and phonetic differences.
9.	Cosentyx	58	This name pair has sufficient orthographic differences. Phonetically, the third syllables (toe vs. ix) of this name pair sound different.
10.	Oxaydo	58	This name pair has sufficient orthographic and phonetic differences.
11.	Saxenda	58	Orthographically, the first letters ‘C’ <i>versus</i> ‘S’ look different. Additionally, the name Coxanto has a cross stroke letter ‘t’ in the sixth position which offers some orthographic difference. Phonetically, the first (cox <i>versus</i> sax) and third (toe <i>versus</i> da) syllables sound different. Additionally, the products differ in strength (300 mg <i>versus</i> 18 mg/3 mL), dosage form (capsule <i>versus</i> injection), and route of administration (oral <i>versus</i> subcutaneous), which may help differentiate the products if included on a prescription/order. When all the forementioned mitigations are considered in totality, the risk of name confusion is minimized in this case.

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

No.	Name	POCA Score (%)
		None

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.	(b) (4)	68	(b) (4)
2.	Doxatet	65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Coxiba	64	Veterinary product.
4.	Cloxapen	63	Brand discontinued with no generic equivalents available. ANDA 061806 withdrawn FR effective 06/04/2018 and ANDA 062233 withdrawn FR effective 04/07/1999.
5.	Coactin	63	Brand discontinued product with no available generics. NDA 050565 withdrawn FR effective 10/02/1996.
6.	(b) (4)	62	(b) (4)
7.	Oxanid	62	International product formerly marketed in the United Kingdom.
8.	(b) (4)	62	(b) (4)
9.	Mitoxana	61	International product marketed in the United Kingdom and Ireland.
10.	1-Octanol	60	Product is not a drug. Product is an organic compound.
11.	2-Octanol	60	Product is not a drug. Product is an organic compound.
12.	Conacetol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
13.	Consensi	60	Brand discontinued with no generic equivalents available. The Applicant submitted a voluntary withdrawal for approval of an application request for NDA 210045 on July 27, 2022.
14.	Coracten	60	International drug product marketed in Hong Kong and United Kingdom and formerly marketed in Thailand and Greece.
15.	Octoxynol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Octoxynol-1	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Octoxynol-11	60	This product is not a drug. It is a bamboo extract used as a detergent and stain remover.
18.	Octoxynol-40	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Octoxynol-5	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Octoxynol-7	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Octoxynol-8	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Octoxynol-9	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Catacand	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	Captan	58	Product is not a drug. It is a pesticide that belongs to the phthalimide class of fungicides.
25.	Cinoxacin	58	Brand discontinued with no generic equivalents available. NDA 018067 withdrawn FR effective 4/4/2005.
26.	Cinoxate	58	Product is not a drug. It is a compound used in sunscreen.
27.	Coconut Oil	58	Product is not a drug.
28.	Codafen	58	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
29.	Combantrin	58	International product marketed in Austria, Australia, New Zealand, Philippines, Canada, Italy, Mexico, Portugal, Venezuela, Japan, and France; formerly marketed in South Africa, Chile, Greece, Hong Kong, Indonesia, Israel, Thailand, and the United Kingdom.
30.	Comixco	58	International product marketed in the United Kingdom.
31.	Conffits	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Contimin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Cophene No. 2	58	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
34.	Coro-Nitro	58	International drug product marketed in the United Kingdom and formerly marketed in Germany.
35.	(b) (4)	58	(b) (4)
36.	Cotab Ax	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
37.	Cotameth	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
38.	Endoxan	58	Internationally marketed product in Czech Republic, Germany, Russia, Singapore, Australia, Austria, Belgium, Chile, China, France, Hong Kong, Hungary, Israel, Italy, New Zealand, Netherlands, Poland, Portugal, Switzerland, Thailand, Ukraine, India, Turkey, Japan, Indonesia, the United Kingdom, and Ireland; formerly marketed in Malaysia, Greece, the Philippines, Argentina, and South Africa.
39.	Endoxana	58	International product marketed in the United Kingdom and Ireland and formerly marketed in Ireland.
40.	Gantanol	58	Brand discontinued with no generic equivalents available. NDA 012715 withdrawn FR effective 09/17/2001.

No.	Name	POCA Score (%)	Failure preventions
41.	Kepvance	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
42.	Norplant	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
43.	Octinoxate	58	Product is not a drug. It is a compound used in sunscreen.
44.	Seroxat	58	International product marketed in Austria, Belgium, China, Czech Republic, Denmark, Finland, Germany, Greece, Hong Kong, Hungary, Ireland, Israel, Italy, Malaysia, Netherlands, Norway, Philippines, Poland, Portugal, Singapore, Spain, Sweden, Thailand, the United Kingdom, and Turkey; formerly marketed in Indonesia.
45.	(b) (4)	58	(b) (4)
46.	Toloxatone	58	International product formerly marketed in Italy and France.
47.	Xanthomax	58	International product marketed in the United Kingdom.
48.	Coversyl	35	International product marketed in Canada, France, Chile, Japan, Denmark, Mexico, Australia, Belgium, Brazil, Finland, Ireland, Italy, Malaysia, Netherlands, Philippines, Portugal, South Africa, Singapore, Spain, Turkey, United Kingdom, Venezuela, Greece, New Zealand, Thailand, and Denmark.

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.	Oxecta	62
2.	Docosanol	60
3.	Doxidan	60

^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 (%)
4.	Doconexent	59
5.	Moxatag	59
6.	Oxivent	59
7.	Katinko	58
8.	Noxivent	58
9.	Oxistat	58
10.	Oxymeta-12	58
11.	Troxyca	58
12.	(b) (4)	57
13.	Moctanin	57
14.	Nucynta	56
15.	Picato	56
16.	Taxadone	56
17.	Texacort	56
18.	Tokisan	56
19.	1-Octacosanol	55
20.	Nacton	55
21.	Oxycontin	55
22.	Take Control	55

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/s/

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