CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209511Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 16, 2020
Application Type and Number:	NDA 209511
Product Name and Strength:	Xaracoll (bupivacaine HCl collagen-matrix implants) implant, 100 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Innocoll Pharmaceuticals (Innocoll)
Panorama #:	2020-38137485
DMEPA Safety Evaluator:	Cameron Johnson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xaracoll, 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. Innocoll did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Innocoll previously submitted the proposed proprietary name, Xaracoll, for review on May 8, 2015. The proposed proprietary name, Xaracoll, was found to be conditionally acceptable under IND 077127 on July 29, 2015[a]. Innocoll then submitted the proposed proprietary name, Xaracoll on February 7, 2018 under NDA 209511. We found the name, Xaracoll*** conditionally acceptable on May 2, 2018.[b] However, on November 30, 2018 a complete response (CR) letter was issued for NDA 209511 due to nonclinical and product quality deficiencies. On February 26, 2020, Innocoll submitted their responses to the deficiencies included in the CR letter as a Class 2 resubmission. Thus on February 27, 2020, Innocoll submitted the proposed proprietary name, Xaracoll, for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 27, 2020.

- Intended Pronunciation: ZAIR uh coll
- Active Ingredient:bupivacaine HCl
- Indication of Use: placement into the surgical site in adults to produce postsurgical local analgesia following open inguinal hernia repair
- Route of Administration: surgical implantation
- Dosage Form: implant
- Strength: 100 mg
- Dose and Frequency: 300 mg (3 x 100 mg implants) cut in half and placed into surgical site (place three halves below the site of mesh placement and three halves just below skin closure)
- How Supplied: Four single-use cartons, each containing one pouch containing 3 x 100 mg implants and Ten single-use cartons, each containing one pouch containing 3 x 100 mg implants

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[a] Shah, M. Proprietary Name Review for Xaracoll*** (IND 077127). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 JUL 29. OSE RCM No. 2015-395678

[b] Johnson, C. Proprietary Name Review for Xaracoll*** (NDA 209511). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAY 02. Panorama No. 2018-20874799.

- Storage: 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Xaracoll would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Xaracoll.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Innocoll indicated in their submission that the prefix "Xara-", of the proposed name, Xaracoll, has no significant meaning. However, the suffix "coll" (b) (4) (b) (4) (b) (4) 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, March 11, 2020 e-mail, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Xaracoll at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-one practitioners participated in DMEPA's prescription studies for Xaracoll. In the verbal study, one participant interpreted Xaracoll as "Veracol" and one participant interpreted Xaracoll as "Zerochol". We evaluated these names and determined that the risk of confusion will be mitigated because both Veracol and Zerochol are international products. Therefore, neither of these products would coexist with Xaracoll in the U.S market. See Appendix C and Appendix G

[c] USAN stem search conducted on March 6, 2020.

for our assessment of these names. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 234 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 3 names not previously analyzed. 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 the 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 ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	4
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 5 names contained in Table 1 determined none of the names will pose a risk for confusion with Xaracoll 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 Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) via e-mail on April 8, 2020. At that time we also requested additional information or concerns that could inform our review. The Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any additional concerns with the proposed proprietary name, Xaracoll.

[d] POCA search conducted on March 6, 2020 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Xaracoll, is acceptable.

If you have any questions or need clarifications, please contact Tamika White, OSE project manager, at 301-796-0310 .

3.1 COMMENTS TO INNOCOLL PHARMACEUTICALS

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

In addition we have the following comments related to your product:

In your Request for Proprietary Name Review, you state that the suffix, 'coll' of the proposed proprietary name, Xaracoll, is (b) (4) (b) (4) Because this seems to be the first instance where you proposed a name containing the suffix 'coll' in the U.S market, we do not object to the inclusion of 'coll' in this proposed name. However, we recommend the following if you have plans for future product development:

> As you develop proprietary names for future products, please note the practice of including the identical letter string '-coll' in the proprietary name can result in creating multiple similar proprietary names, which might increase the risk of name confusion among your products. For more information, please see the Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs (2014) available at: https://www.fda.gov/downloads/drugs/guidances/ucm398997.pdf

If any of the proposed product characteristics as stated in your submission, received on February 27, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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[e] 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[f]. 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.

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

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. 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. Xaracoll Study (Conducted on March 13, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: Xaracoll Implant 300 mg for procedure Outpatient Prescription: Xaracoll use as directed Dispense #1	Xaracoll Use as directed Dispense # 1
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Xaracoll	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study
91 People Responded

Study Name: Xaracoll

Total	**19**	**33**	**19**	**20**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
VERACOL	0	0	1	0	1
VIROCALL	0	0	1	0	1
XARACALL	1	0	0	0	1
XARACELL IMPLANT	0	0	0	1	1
XARACIL IMPLANT	0	0	0	3	3
XARACOIL IMPLANT	0	0	0	5	5

XARACOLE	2	0	0	0	2
XARACOLL	16	33	0	3	52
XARACOLL IMPLANT	0	0	0	6	6
XAVACIL IMPLANT	0	0	0	1	1
XERACOL	0	0	2	0	2
XEROCALL	0	0	1	0	1
XEROCOL	0	0	3	0	3
YARACOLL IMPLANT	0	0	0	1	1
ZERACHOL	0	0	1	0	1
ZERACOL	0	0	4	0	4
ZERICAL	0	0	1	0	1
ZERICOL	0	0	1	0	1
ZEROCALL	0	0	1	0	1
ZEROCHOL	0	0	1	0	1
ZEROCOL	0	0	2	0	2

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

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** implant **Strength(s):** 100 mg **Usual Dose:** 300 mg (3 x 100 mg implants) cut in half and placed into surgical site (place three halves below the site of mesh placement and three halves just below skin closure)	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.	Veracol	84	International product marketed in several countries.

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 (%)
	N/A	

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

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** implant **Strength(s):** 100 mg **Usual Dose:** 300 mg (3 x 100 mg implants) cut in half and placed into surgical site (place three halves below the site of mesh placement and three halves just below skin closure)	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**
2.	SurePal***	59	This name pair has sufficient orthographic and phonetic differences.
3.	Arakoda	56	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 (%)
	N/A	

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
4.	Carvacrol	68	This is not a drug. This is a phenol found in essential oil of thyme, oregano, pepperwort, and wild bergamot.
5.	Zerochol	66	International product marketed in Ireland.

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

No.	Name	POCA Score (%)
6.	N/A	

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CAMERON D JOHNSON
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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Innocoll Pharmaceuticals
Panorama #:	2018-20874799
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Xaracoll, 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 did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant submitted the proposed proprietary name, Xaracoll, for review on May 8, 2015. The proposed proprietary name, Xaracoll, was found to be conditionally acceptable under IND 077127 on July 29, 2015[a]. The Applicant has now submitted the name for review under the NDA.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 7, 2018.

- Intended Pronunciation: Zair uh coll
- Active Ingredient: bupivacaine HCl
- Indication of Use: placement into the surgical site to produce postsurgical analgesia following (b) (4)
- Route of Administration: surgical implantation
- Dosage Form: collagen-matrix implant
- Strength: 100 mg
- Dose and Frequency: 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain
- How Supplied: Three sterile surgical implants (approximately 5 cm x 5 cm x 0.5 cm), each containing 100 mg of bupivacaine HCl in individually sealed blisters. A tray of three blisters in a sterile pouch is provided in one carton.
- Storage: Room temperature
- Reference Listed Drug/Reference Product: Marcaine (bupivacaine HCl injection NDA (b) (4)

[a] Shah, M. Proprietary Name Review for Xaracoll*** (IND 077127). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 JUL 29. OSE RCM No. 2015-395678

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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the prefix "Xara-", of the proposed name, Xaracoll, has no significant meaning. However, the suffix "coll" is (b) (4) (b) (4) (b) (4) 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, February 22, 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

Ninety-two practitioners participated in DMEPA's prescription studies. In the verbal study, one participant interpreted Xaracoll as "Zeroqual" and stated that the name "reminds me of seroquel". Another participant from the verbal study interpreted the prescription as "Zeraqual". Both responses sound similar to the currently marketed product Seroquel. Our analysis of the name pair, Xaracoll and Seroquel, determined that the risk of confusion will be mitigated based on the orthographic and product characteristic differences. See Appendix E for our assessment of the name pair. Appendix B contains the results from the verbal and written prescription studies.

[b] USAN stem search conducted on (2/12/2018).

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 232 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 and FDA Prescription Simulation 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%	12
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	212
Low similarity name pair: combined match percentage score ≤54%	9

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

Our analysis of the 233 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 April 19, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on April 30, 2018, they stated no additional concerns with the proposed proprietary name, Xaracoll.

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.

[c] POCA search conducted on (2/12/2018) in version 4.2.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on February 7, 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Xaracoll Study (Conducted on 2/21/2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Xaracoll Implant 300 mg for procedure Outpatient Prescription: Xaracoll Use as directed Bring to clinic Disp: #1	Xaracoll Use as directed Bring to clinic Dispense # 1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Xaracoll

306 People Received Study

92 People Responded

Total	**30**	**30**	**32**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
SERACOLL	0	1	0	1
SEROCAL	0	1	0	1
SEROCALL	0	1	0	1
XAIACOLL	0	0	1	1
XANACOLL IMPLANT	0	0	1	1

XARACALL	3	0	0	3
XARACOLL	27	0	5	32
XARACOLL IMPLANT	0	0	23	23
XARACOLT	0	0	1	1
XASACOLL IMPLANT	0	0	1	1
XERACOL	0	3	0	3
XERICAL	0	2	0	2
XEROCOL	0	1	0	1
ZARACOL	0	1	0	1
ZARCAL	0	1	0	1
ZERACAL	0	1	0	1
ZERACALL	0	2	0	2
ZERACHOL	0	1	0	1
ZERACOL	0	6	0	6
ZERAQUAL	0	1	0	1
ZERECHOL	0	1	0	1
ZERICAL	0	2	0	2
ZERICOL	0	4	0	4
ZEROQUAL	0	1	0	1

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

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen-matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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.	Xaracoll	100	Name is subject of this review.
2.	Zeranol	70	This is a veterinary implant product used to increase weight gain and improve feed conversion of beef cattle.
3.	Thoracol	74	The prefixes of this name pair look different (Thor- vs Xar-) because there is an upstroke 'h' in the second position of Thoracol. The first syllable of Thoracol contains the "Th" sound while the first syllable of Xaracoll contains the "Za" sound. Xaracoll is a prescription medication that is only used in the surgical setting while Thoracol is an over-the-counter medication used in the outpatient and inpatient setting. Xaracoll is implanted into the surgical site one time while Thoracol can be administered every two hours as needed.

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen-matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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.**
4.	Sarisol	70	The prefixes of the name pair look different (Sar- vs Xar-) because the names begin with different first letters (S- vs X-). The last syllables sound different when pronounced (sol vs coll). Xaracoll is implanted into the surgical site one time in the surgical setting while Sarisol is a chronic medication used multiple times a day at home or at the bedside in the inpatient setting.
5.	Murocoll 2	70	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available. Product was an ophthalmic solution containing phenylephrine HCl (b) (4) % and scopolamine HBr (b) (4) %.
6.	Lavacol	74	This is a formerly marketed brand of 70% ethanol (rubbing alcohol) that is not expected to be ordered by proprietary name on a prescription. The prefixes of the name pair look different (Lav- vs Xar-) because the names begin with different first letters (L- vs X-). The onsets of the first and second syllables sound different when pronounced (lava vs xara).

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen-matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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.**
7.	Labrocol	72	International product marketed in the
8.	Garasol	74	
9.	(b) (4)	82	(b) (4)
10.	Dermacool	71	
11.	Baratol	78	International product marketed in United Kingdom, South Africa, and Ireland.
12.	Alacol	72	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.

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 (%)
13.	Xalkori	58
14.	Tracleer	55
15.	Tetrachel	60
16.	Terazol 3	65
17.	Keratol	68
18.	Dilacor	63
19.	Citracal	66

No.	Name	POCA Score (%)
20.	Carbachol	66
21.	Aranelle	56
22.	Ala-Cort	58
23.	Ricola	62
24.	Cepacol	64

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:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	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.	Xerac AC	64	This name pair has sufficient orthographic and phonetic differences.
26.	Xenical	59	Phonetically, the first syllables of the name pair sound different (Zen vs Zair). The settings and frequency of use for this name pair are sufficiently different. Xaracoll is implanted one time in the operating room while Xenical is a chronic medication given at home or at the bedside in the inpatient setting and administered three times a day.
27.	Xarelto	66	This name pair has sufficient orthographic and phonetic differences.
28.	Xalix	56	This name pair has sufficient orthographic and phonetic differences.
29.	Xadago	55	This name pair has sufficient orthographic and phonetic differences.
30.	Visicol 398/1102	58	This name pair has sufficient orthographic and phonetic differences.
31.	Visicol	58	This name pair has sufficient orthographic and phonetic differences.
32.	Virasal	64	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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**
33.	Veracolate	60	This name pair has sufficient orthographic and phonetic differences.
34.	Vayacog	56	This name pair has sufficient orthographic and phonetic differences.
35.	Vanatol	64	This name pair has sufficient orthographic and phonetic differences.
36.	Vanacof-8	55	This name pair has sufficient orthographic and phonetic differences.
37.	Vanacof	55	This name pair has sufficient orthographic and phonetic differences.
38.	Uroxatral	49	This name pair has sufficient orthographic and phonetic differences.
39.	Toradol	68	This name pair has sufficient orthographic and phonetic differences.
40.	Theracort	55	This name pair has sufficient orthographic and phonetic differences.
41.	Terazol 7	65	This name pair has sufficient orthographic and phonetic differences.
42.	Spacol	60	This name pair has sufficient orthographic and phonetic differences.
43.	Sotradecol	58	This name pair has sufficient orthographic and phonetic differences.
44.	Scalacort	56	This name pair has sufficient orthographic and phonetic differences.
45.	Roxanol	54	This name pair has sufficient orthographic and phonetic differences.
46.	Proxacol	61	This name pair has sufficient orthographic and phonetic differences.
47.	Paramol	68	This name pair has sufficient orthographic and phonetic differences.
48.	Paracort	63	This name pair has sufficient orthographic and phonetic differences.
49.	Panscol	55	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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**
50.	Masoprocol	57	This name pair has sufficient orthographic and phonetic differences.
51.	Laractone	55	This name pair has sufficient orthographic and phonetic differences.
52.	Keratol 40	68	This name pair has sufficient orthographic and phonetic differences.
53.	Ferosul	58	This name pair has sufficient orthographic and phonetic differences.
54.	Durasal	60	This name pair has sufficient orthographic and phonetic differences.
55.	Duraclon	58	This name pair has sufficient orthographic and phonetic differences.
56.	Dermatol 10	64	This name pair has sufficient orthographic and phonetic differences.
57.	Colazal	56	This name pair has sufficient orthographic and phonetic differences.
58.	Citracal + D	58	This name pair has sufficient orthographic and phonetic differences.
59.	Chloracol	68	This name pair has sufficient orthographic and phonetic differences.
60.	Cheracol D	67	This name pair has sufficient orthographic and phonetic differences.
61.	Charcoal	68	This name pair has sufficient orthographic and phonetic differences.
62.	Carteolol	54	This name pair has sufficient orthographic and phonetic differences.
63.	Carmol-40	61	This name pair has sufficient orthographic and phonetic differences.
64.	Carmol-20	61	This name pair has sufficient orthographic and phonetic differences.
65.	Carmol-10	61	This name pair has sufficient orthographic and phonetic differences.
66.	Carmol	61	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Xaracoll **Established name:** bupivacaine HCl collagen-matrix implants **Dosage form:** collagen matrix implant **Strength(s):** 100 mg **Usual Dose:** 300 mg placed at (b) (4) (b) (4) that can be cut using sterile technique before placement into the surgical site at the source of pain	**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**
67.	Carbatrol	62	This name pair has sufficient orthographic and phonetic differences.
68.	Carbacot	58	This name pair has sufficient orthographic and phonetic differences.
69.	Carac	56	This name pair has sufficient orthographic and phonetic differences.
70.	Baraclude	61	This name pair has sufficient orthographic and phonetic differences.
71.	Ascor L 500	55	This name pair has sufficient orthographic and phonetic differences.
72.	Aloral	56	This name pair has sufficient orthographic and phonetic differences.
73.	Airacof	60	This name pair has sufficient orthographic and phonetic differences.
74.	Asacol	66	This name pair has sufficient orthographic and phonetic differences.
75.	Seroquel	54	Orthographically, the prefixes of the name pair (Ser- vs. Xar-) look different because the names begin with different first letters (S- vs. X-). The suffixes (-quel vs. coll) look different because Seroquel has one downstroke letter “q” in the 5th position while Xaracoll has the letter “c” in the 5th position. Xaracoll is implanted one time in the operating room while Seroquel is a chronic medication given at home or at the bedside in the inpatient setting.
76.	Tearisol	58	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 (%)
	N/A	

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
77.	Xylitol	60	This is not a drug. It is a naturally occurring sugar alcohol found in plants and used as a sweetener in gums, mints and candies.
78.	Xatral Sr	58	International product marketed in Australia.
79.	Viranol	68	Name identified in RxNorm and Redbook database. Product is deactivated and there are no generics available.
80.	Veracur	64	International product marketed in United Kingdom.
81.	Uracil	58	Product is not a drug. It is a compound that makes up ribonucleic acid found in living tissue.
82.	Triac cold	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
83.	Tiratricol	56	This is an international thyroid product marketed in European countries.
84.	Surital	60	Brand discontinued with no generic equivalent available. NDA 007600 withdrawn FR effective 09/17/2001.
85.	(b) (4)	58	Proposed proprietary name withdrawn by the applicant. ANDA 209584 received a complete response on December 29, 2017 and no new names have been submitted.
86.	(b) (4)	58	Proposed proprietary name withdrawn by the applicant. Product approved under new proprietary name Kevzara under BLA 761037.
87.	Practolol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
88.	Paral	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
89.	Oxy Oral	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
90.	Oxaceprol	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
91.	Marax	55	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
92.	Guacol	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
93.	Glaucol	60	International product marketed in Austria and United Kingdom.
94.	(b) (4)	64	Proposed name, (b) (4) withdrawn by the applicant. Product approved under new proprietary name Delzicol under NDA 204412.
95.	Dermacool Hc	58	Veterinary product used for dogs, cats and horses.
96.	Corzall	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
97.	(b) (4)	64	Brand discontinued with no generic equivalent available. NDA 019204 withdrawn FR effective 7/8/2011.
98.	Carazolol	62	This is a beta blocker agent used in veterinary medicine.
99.	Calafol Rx	50	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
100.	Baycol	62	Brand discontinued with no generic equivalent available. NDA 02070 withdrawn FR effective 8/18/2017.
101.	Arco-Lase	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
102.	Arachils Oil	58	This product is not a drug. This is another term for peanut oil.
103.	Antrocol	62	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
104.	Acerola	56	This is not a drug. It is a plant that produces fruit rich in vitamin C. There are various dietary supplements containing vitamin C that have the name Acerola.
105.	Loxapac	44	International product marketed in Canada, France, Italy, Spain, Greece, Ireland, Belgium, Denmark, Netherlands, New Zealand, and United Kingdom.
106.	Guaiacol	60	Product is not a drug. It is an organic compound used to add flavor to other products such as whiskey and roasted coffee.
107.	Zorac	58	This is an international product marketed in Germany, Austria, Brazil, Ireland, Sweden, Greece, Israel, Belgium, Switzerland, Australia, and United Kingdom.
108.	Relacon Lax	52	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
109.	Parasal	65	Brand discontinued with no generic equivalents available. NDA 006811 withdrawn FR effective 08/13/1990.
110.	Bracco	59	This is not a drug. This is the name of a company that develops diagnostic imaging products.

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

No.	Name	POCA Score (%)
111.	Tabradol	65
112.	Vanachol	64
113.	Daricon	63
114.	Mardol	63
115.	Circanol	63
116.	Vaprisol	62
117.	Marinol	62
118.	Salamol	62
119.	Fazaclo	62

[f] 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 (%)
120.	Trexall	62
121.	Aridol	62
122.	Foradil	61
123.	Pharbetol	61
124.	Soyacal 10%	61
125.	Soyacal 20%	61
126.	Florical	61
127.	Carbopol 981	61
128.	Citrical	60
129.	Farnesol	60
130.	Zamadol	60
131.	Fortical	60
132.	Valrox	60
133.	Allersol	60
134.	Darcalma	60
135.	Wartrol	60
136.	Largactil	60
137.	Oraxyl	60
138.	Roccal	60
139.	Roc-Cal	60
140.	Cetraxal	59
141.	Corticool	59
142.	Normasol	59
143.	Tobrasol	59
144.	Narcof	59
145.	Terrasil	58
146.	Levatol	58
147.	Ferocyl	58
148.	Kerasal	58
149.	Farbital	58
150.	Barbital	58
151.	Pharmasal	58
152.	Farlutal	58
153.	Natrecor	58
154.	Sarkosyl	58
155.	Bedranol	58
156.	Versacloz	58
157.	Zaroxolyn	58
158.	Vayarol	58
159.	Marcof	58
160.	Cebatrol	58
161.	Tricosal	58
162.	Orgafol	58

No.	Name	POCA Score (%)
163.	Pravachol	58
164.	Rexall	58
165.	Tricalm	57
166.	Broxil	57
167.	Virazole	57
168.	Ceraxon	57
169.	Fortral	57
170.	Flexall	57
171.	Trancopal	57
172.	Durezol	56
173.	Perisol	56
174.	Bellatal	56
175.	Thera-Sal	56
176.	Veraseal	56
177.	Cerovel	56
178.	Malatal	56
179.	Silanol	56
180.	Farnesal	56
181.	Valicot	56
182.	Drontal	56
183.	Fiortal	56
184.	Gardasil	56
185.	Gardasil 9	56
186.	Zithranol	56
187.	Parsidol	56
188.	Cresol	56
189.	Danazol	56
190.	Geraniol	56
191.	Purgasol	56
192.	Bromatol	56
193.	Orajel	56
194.	Afrinol	56
195.	Renocal	56
196.	Renocal-76	56
197.	Parlodel	56
198.	Travasol	56
199.	Travasol 10	56
200.	Travasol 2.75	56
201.	Travasol 2.75/5	56
202.	Travasol 3.5	56
203.	Travasol 4.25/10	56
204.	Travasol 4.25/25	56
205.	Travasol 4.25/5	56

No.	Name	POCA Score (%)
206.	Travasol 5.5	56
207.	Travasol 8.5%	56
208.	Cardinol	56
209.	Doral	56
210.	Adrucil	56
211.	Dexasol	56
212.	Calpol	56
213.	Cortalo	56
214.	Adderall	56
215.	Adderall 10	56
216.	Adderall 12.5	56
217.	Adderall 15	56
218.	Adderall 20	56
219.	Adderall 30	56
220.	Adderall 5	56
221.	Adderall 7.5	56
222.	Clearsol	56
223.	Drixoral	56
224.	Allercon	46
225.	Lopranol La	44
226.	Celectol	63
227.	Claripel	57
228.	Percutol	57
229.	Carticel	51
230.	Akrinol	50
231.	Ray Dol	46
232.	Ambroxol	44
233.	Lactocal	44

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/s/

CAMERON D JOHNSON
05/02/2018

OTTO L TOWNSEND
05/02/2018