CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210872Orig1s000

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:	March 1, 2019
Application Type and Number:	NDA 210872
Product Name and Strength:	ZuraGard (Isopropyl Alcohol) Solution, 70%
Product Type:	Single Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	Zurex Pharma (Zurex)
Panorama #:	2018-27767623
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Zurex previously submitted the proposed proprietary name, ZuraPrep*** on June 29, 2018. However, we found the name, ZuraPrep***, unacceptable [redacted] on September 25, 2018.[a]

Thus, Zurex, submitted the name, ZuraGard, for review on December 6, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 6, 2018.

- Intended Pronunciation: Zer – ruh – gard
- Active Ingredient: Isopropyl Alcohol
- Indication of Use: For [redacted] preparation of the [redacted] skin prior to surgery. Helps [redacted] reduce bacteria that potentially can cause skin infection.
- Route of Administration: Topical
- Dosage Form: Solution
- Strength: 70%
- Dose and Frequency: Drug Facts Label (DFL) *Directions*
  - remove applicator from package; do not touch sponge
  - hold the applicator sponge down. Depress the end cap/button to release the antiseptic, solution will flow into the sponge
  - [redacted] completely wet the treatment area
  - do not allow solution to pool; tuck prep towels to absorb solution, and then remove
  - dry surgical sites (such as abdomen or arm): use repeated back-forth strokes [redacted] for [redacted] 30 seconds
  - moist surgical sites (such as inguinal fold): use repeated back-forth strokes [redacted] for [redacted] 2 minutes

[a] Jones G. Proprietary Name Review for ZuraPrep (NDA 210872). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 SEP 25. Panorama No. 2018-24256508.

- o [redacted] solution [redacted] completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- o discard the applicator after single use along with any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.

- How Supplied: 10.5 mL applicator
- Storage: Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT & INITIAL COMMENTS

At the initial phase of the review, in response to our initial OSE, December 10, 2018 email, the Division of Nonprescription Drug Products (DNDP) determined that ZuraGard would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) concurred with DNDP's assessment for ZuraGard.

DNDP also provided an initial comment that the proposed proprietary name, ZuraGard, "reminds me a little of the vaccine Gardasil" but ultimately stated that DNDP has no concerns relating to the proposed proprietary name, ZuraGard. The name pair ZuraGard and Gardasil has low similarity with a combined POCA score of 48%; we find the name pair has sufficient orthographic and phonetic differences.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Zurex indicated in their submission that the proposed proprietary name, ZuraGard, is associated with the manufacturer's name, Zurex Pharma, Inc., and the suffix contained in the proposed proprietary name is commonly identified with antiseptic/antimicrobial products for preoperative use. We provide comments to the Applicant in Section 3.1 regarding this name derivation as it relates to their future product development.

[b] USAN stem search conducted on January 3, 2019.

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 FDA Name Simulation Studies

One-hundred and one (101) practitioners participated in DMEPA's prescription studies for ZuraGard. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 108 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.

2.2.5 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	101
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 108 names contained in Table 1 determined none of the names will pose a risk for confusion with ZuraGard as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNDP) via e-mail on February 20, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Nonprescription Drug Products (DNDP) on February 28, 2019, they stated that they have no concerns with the proposed proprietary name, ZuraGard.

[c] POCA search conducted on December 10, 2018 in version 4.2.

3 CONCLUSION

The proposed proprietary name, ZuraGard, is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO ZUREX PHARMA

We have completed our review of the proposed proprietary name, ZuraGard, 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 derivation of your proposed proprietary name, ZuraGard, is associated with the manufacturer's name, Zurex Pharma, Inc. We understand that the proposed isopropyl alcohol product is your first NDA submission (b) (4) :

Proprietary names should not incorporate the sponsor's name across multiple products (e.g., ABCName1, ABCName2, ABCName3, etc.). This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. The practice can be problematic when products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists. 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 December 6, 2018, 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. 6F[d]

*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)).

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

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 names7F[e]. We evaluate all moderately similar names retrieved from POCA to

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary

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.

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.

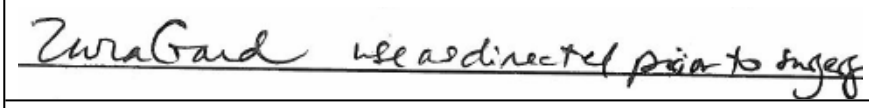
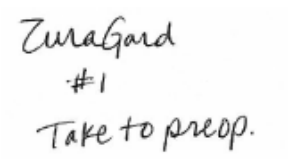
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. ZuraGard Study (Conducted on January 11, 2019January 11, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	ZuraGard Take to preop Dispense 1
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

304 People Received Study

101 People Responded

Study Name: Zuragard

Total 59 16 26

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
SERAGARD	0	1	0	1
SEROGUARD	0	1	0	1
XEROGUARD	0	1	0	1
ZEGAGARD	0	1	0	1
ZERAGARD	0	1	0	1
ZERAGUARD	0	2	0	2
ZEREGARD	0	2	0	2
ZERIGARD	0	1	0	1
ZEROGARD	0	1	0	1
ZEROGAURD	0	1	0	1
ZINAGARD	2	0	0	2
ZUNAGARD	3	0	0	3
ZURAGARD	52	1	23	76
ZURAGAUD	0	0	1	1
ZURAGORD	1	0	0	1
ZURAGUARD	1	1	0	2
ZUREGARD	0	1	0	1
ZURGARD	0	0	1	1
ZURIGARD	0	1	0	1
ZWIAGARD	0	0	1	1

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

No.	Proposed name: ZuraGard Established name: Isopropyl Alcohol Dosage form: Solution Strength(s): 70% Usual Dose: Use repeated back-forth strokes of the sponge for approximately 30 seconds for dry surgical sites and for approximately 2 minutes for moist sites	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.	3M Avagard	70	3M is the manufacturer of the product and the product name is Avagard (see Appendix E for evaluation of Avagard).
2.	Corgard	72	Orthographically, the first letters ('z' vs. 'c') of this name pair are sufficiently different when written. Additionally, ZuraGard contains an additional letter ('a') in the fourth letter position, which further differentiates the infix of the name pair. Phonetically, ZuraGard contains 3 syllables whereas Corgard contains 2 syllables. The onset of the letters in the first syllables of the name pair sound different ('Zur-' vs. 'Cor-') ZuraGard does not overlap in product characteristics with Corgard: Strength (70% vs. 20 mg, 40 mg, and 80 mg), Dosage form (topical solution vs. tablets), Route of administration (topical vs. oral), and Frequency of administration (prior to surgery vs. once daily). Thus, these additional non-overlapping product characteristics also minimize the risk of name confusion between the name pair.
3.	Duragal-S	74	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Neutragard	78	Orthographically, in the prefix, the letters 'Zu' vs. 'Neut' of this name pair are sufficiently different. Phonetically, the first syllables ('Zer-' vs. 'New-') of the name pair sound different.

No.	Proposed name: ZuraGard Established name: Isopropyl Alcohol Dosage form: Solution Strength(s): 70% Usual Dose: Use repeated back-forth strokes of the sponge for approximately 30 seconds for dry surgical sites and for approximately 2 minutes for moist sites	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.
5.	Relagard	74	Orthographically, first letters ('Z' vs. 'R') and the third letters ('r' vs. 'l') of this name pair are sufficiently different when written. Additionally, this third letter in Relagard ('l') provides the infix of the name pair a different shape. Phonetically, the first syllables ('Zer-' vs. 'Rel-') of this name pair sound different.
6.	zuragard	100	Proposed proprietary name that is the subject of this review.

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 (%)
7.	Dura Ron	59
8.	Duraclon	55
9.	Duragen	65
10.	Duramorph	62
11.	Duratest	58
12.	Eligard	60
13.	Folgard	66
14.	Gammagard	66
15.	Haegarda	59
16.	Zegerid	56
17.	Zinecard	63

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: ZuraGard Established name: Isopropyl Alcohol Dosage form: Solution Strength(s): 70% Usual Dose: Use repeated back-forth strokes of the sponge for approximately 30 seconds for dry surgical sites and for approximately 2 minutes for moist sites	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
18.	Aloeguard	60	This name pair has sufficient orthographic and phonetic differences.
19.	Ana-Guard	62	This name pair has sufficient orthographic and phonetic differences.
20.	Avagard	68	This name pair has sufficient orthographic and phonetic differences.
21.	Avagard D	67	This name pair has sufficient orthographic and phonetic differences.
22.	Caroguard	67	This name pair has sufficient orthographic and phonetic differences.
23.	Dragon	56	This name pair has sufficient orthographic and phonetic differences.
24.	Duradrin	66	This name pair has sufficient orthographic and phonetic differences.
25.	Duraprep	60	This name pair has sufficient orthographic and phonetic differences.
26.	Durasal	57	This name pair has sufficient orthographic and phonetic differences.
27.	Dura-Tap Pd	65	This name pair has sufficient orthographic and phonetic differences.
28.	Duratuss G	62	This name pair has sufficient orthographic and phonetic differences.
29.	Durlaza	56	This name pair has sufficient orthographic and phonetic differences.
30.	Fluorigard	67	This name pair has sufficient orthographic and phonetic differences.
31.	Fungi-Guard	58	This name pair has sufficient orthographic and phonetic differences.
32.	Micro-Guard	60	This name pair has sufficient orthographic and phonetic differences.
33.	Paragard T 380A	66	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: ZuraGard Established name: Isopropyl Alcohol Dosage form: Solution Strength(s): 70% Usual Dose: Use repeated back-forth strokes of the sponge for approximately 30 seconds for dry surgical sites and for approximately 2 minutes for moist sites	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
34.	Periguard	67	This name pair has sufficient orthographic and phonetic differences.
35.	Periogard	64	This name pair has sufficient orthographic and phonetic differences.
36.	Radiaguard	63	This name pair has sufficient orthographic and phonetic differences.
37.	Raw Sugar	56	This name pair has sufficient orthographic and phonetic differences.
38.	Run Guard	64	This name pair has sufficient orthographic and phonetic differences.
39.	Sani Guard	62	This name pair has sufficient orthographic and phonetic differences. Phonetically, the second syllables of this name pair sound different.
40.	Smileguard	56	This name pair has sufficient orthographic and phonetic differences.
41.	Stangard	63	This name pair has sufficient orthographic and phonetic differences.
42.	Trogarzo	62	This name pair has sufficient orthographic and phonetic differences.
43.	Vistogard	58	This name pair has sufficient orthographic and phonetic differences.
44.	Z-Guard	69	This name pair has sufficient orthographic and phonetic differences.
45.	Zirgan	62	This name pair has sufficient orthographic and phonetic differences.
46.	Zurampic	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 (%)
47.	Agar	49

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
48.	Acuguard	60	Veterinary product.
49.	Auralgan	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
50.	Auroguard	69	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
51.	Cedocard	56	International product marketed in Indonesia, Belgium and United Kingdom.
52.	Centragard	66	Veterinary product.
53.	Durabac	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
54.	Duract	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
55.	Durad	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	Duradal Hd	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
57.	Duradex	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
58.	Durafed	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
59.	Duraganidin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Duranest	58	Name identified in Drugs@FDA database and RxNorm database. Brand discontinued with no generic equivalents available.
61.	Duraquin	56	Name identified in Drugs@FDA database. Brand discontinued with no generic equivalents available.
62.	Duratan	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
63.	Duratuss Da	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
64.	Duratuss Dm	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
65.	Duratuss Hd	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
66.	Duraxin	56	International product formerly marketed in Puerto Rico.
67.	Duro Cort	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
68.	Eligard 22.5	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
69.	Eligard 30	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
70.	Eligard 45	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
71.	Eligard 7.5	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	Estraguard	64	Name identified in Drugs@FDA database. Brand discontinued with no generic equivalents available.
73.	Flura-Tab	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
74.	Fragarin	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Heartgard	57	Veterinary product.
76.	Nexgard	58	Veterinary product.
77.	Nitrogard	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
78.	Norocarp	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
79.	Orgaran	59	Name identified in Drugs@FDA database and RxNorm database. Brand discontinued with no generic equivalents available.
80.	Oxy Gard	57	Veterinary product.
81.	Quadriguard	62	Veterinary product.
82.	Safe-Guard	64	Veterinary product.
83.	Shade Uvaguard	57	Name identified in Drugs@FDA database. Brand discontinued with no generic equivalents available.
84.	Suscard	62	International product marketed in Sweden.
85.	Teat Guard	58	Veterinary product.
86.	Ulcergard	68	Veterinary product.
87.	Xylocard	59	International product marketed in Australia, Belgium, Canada, France, India, Singapore, and Sweden.
88.	(b) (4) ***		(b) (4)
89.	Zuraprep***	66	Proposed proprietary name for NDA 210872 found unacceptable by DMEPA (OSE# 2018-24256508). Applicant proposed current name of this review for NDA 210872.

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 (%)
90.	Butabarb	58
91.	Citracal + D	57
92.	Derma Gran	58
93.	Dermagran	58
94.	Fero-Grad	63
95.	Gadaderm	56
96.	Neutra-Germ	58
97.	Nutracort	58
98.	Paracort	56
99.	Pseudacarb	57
100.	Sudan Red	58
101.	Supraderm	62
102.	Surgam	60
103.	Theraderm	55
104.	Tussadur-Hd	56
105.	Uddergold	58
106.	Uracd	56
107.	Veracur	56
108.	Virazid	56

[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

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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:	September 25, 2018
Application Type and Number:	NDA 210872
Product Name and Strength:	ZuraPrep (Isopropyl Alcohol) Solution, 70%
Product Type:	Single Ingredient Product
Rx or OTC:	OTC
Applicant/Sponsor Name:	Zurex Pharma
Panorama #:	2018-24256508
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader (Acting):	Sevan Kolejian, PharmD, MBA
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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