CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208912Orig1s000

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:	July 18, 2017
Application Type and Number:	NDA 208912
Product Name and Strength:	Dexycu (dexamethasone) suspension for intraocular injection, 9%
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Icon Bioscience
Panorama #:	2017-14746072
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Acting Team Leader:	Sarah K. Vee, Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Dexycu, 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 previously submitted the proposed proprietary name, Dexycu, under IND 105562 on September 24, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Dexycu, conditionally acceptable in OSE Review 2015-1594704 on March 14, 2016[a]. The Applicant submitted the NDA on April 12, 2017 and resubmitted the name, Dexycu, for review on April 28, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 28, 2017, proprietary name submission:

- Intended Pronunciation: dex' y kue
- Active Ingredient: dexamethasone
- Indication of Use: (b) (4) for the treatment of postoperative inflammation
- Route of Administration: intraocular
- Dosage Form: suspension for intraocular Injection
- Strength: 9%
- Dose and Frequency: Inject 5 mcL into the (b) (4) behind the iris immediately after the completion of surgery
- How Supplied: each kit contains a single-use 2-cc glass vial with a blue cap designed to deliver 5 mcL of 103.4 mg/mL dexamethasone
- Storage: store at (b) (4)
- Reference Listed Drug (505b2): Maxidex (NDA 13422)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

[a]Rutledge, M. Proprietary Name Review for Dexycu. 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); 2016 03 14 Panorama No. 2015-1594704

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Ophthalmology Products (DTOP) 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 did not provide a derivation or intended meaning for the proposed name, Dexycu in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 18, 2017 e-mail, the clinical reviewer within the Division of Dermatology and Dental Products (DDDP) commented that "the name DEXYCU, pronounced "DEXY QUE" but spelled "DEXY SEE YOU" implies a direct effect on vision and is promotional and misleading. This product will treat inflammation. It will not directly affect vision despite its use in conjunction with cataract surgery." The clinical reviewer's concern was shared with OPDP. OPDP re-reviewed the name taking into account DTOP's concern and maintained their non-objection to the name. We informed DTOP of OPDP's determination and DTOP did not provide any additional comments. DMEPA concurs with OPDP's assessment.

2.2.4 FDA Name Simulation Studies

Seventy one (n=71) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 52 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated 85 names in our previous proprietary name review[d]. We re-evaluated the previously identified names of

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[b]USAN stem search conducted on (June 14, 2017)

[c]POCA search conducted on June 8, 2017 in version 4.0.

[d]Rutledge, M. Proprietary name review for Dexycu (IND 105562). 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); 2016 03 14 p.32 OSE RCM No.: 2015-1594704

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 11 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, proposed name will be available in 9%. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.7 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. 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%	3
Low similarity name pair: combined match percentage score ≤54%	7

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

Our analysis of the 11 names contained in Table 1 determined that 11 names will not pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Ophthalmology Products (DTOP) via e-mail on July 18, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DTOP on July 18, 2017, they noted that they have no other concerns with the name besides the promotional concerns they had noted previously. As outlined in section 2.2.3, DTOP's concerns were shared with OPDP and upon re-review OPDP maintained their non-objection to the name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 28, 2017, submission 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. [e]

[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

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

retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

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

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

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

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
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?
	Considering variations in scripting of		Do the syllables have different

Y/N	some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	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

<table>
<tr><td></td><td colspan="2">which may potentiate confusion between a name pair with moderate similarity.

• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>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?</td><td>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?</td></tr>
</table>

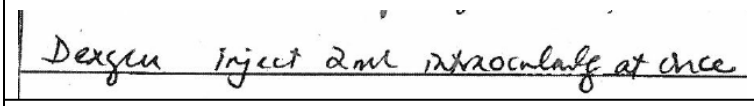
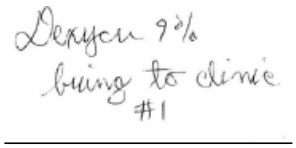
Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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. Dexycu Study (Conducted on May 22, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Dexycu 9% Bring to clinic #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

-

295 People Received Study

71 People Responded

Study Name: Dexycu

Total	**28**	**23**	**20**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DEXEQ	0	1	0	1
DEXEQUE	0	1	0	1
DEXGAN	0	0	1	1
DEXGEN	0	0	6	6
DEXGEU	0	0	2	2
DEXGIN	0	0	1	1
DEXGLU	0	0	7	7
DEXGUN	0	0	1	1
DEXICUE	0	6	0	6
DEXICUE 9%	0	1	0	1
DEXI-Q	0	1	0	1
DEXIQUE	0	8	0	8
DEXIQUE 9%	0	1	0	1
DEXIQUEUE	0	1	0	1
DEXIQUI	0	1	0	1
DEXQUE	0	0	1	1
DEXSIQUE	0	1	0	1

DEXY Q	0	1	0	1
DEXYCIN	4	0	0	4
DEXYCN	4	0	0	4
DEXYCU	16	0	0	16
DEXYCU 9%	1	0	0	1
DEXYEN	1	0	0	1
DEXYGEN	0	0	1	1
DEXYOU	1	0	0	1
DOXYCU	1	0	0	1

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

No.	**Proposed name:** Dexycu **Established name:** dexamethasone **Dosage form:** suspension for intraocular injection **Strength(s):** 9% **Usual Dose:** Inject 5 mcL into the (b) (4) behind the iris immediately after the completion of surgery	**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.	Dexycu	100	Proprietary name 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-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:** Dexycu **Established name:** dexamethasone **Dosage form:** suspension for intraocular injection **Strength(s):** 9% **Usual Dose:** Inject 5 mcL into the (b) (4) behind the iris immediately after the completion of surgery	**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.	Udenyca***	58	Both names start with different letters. Udenyca has an upstroke ('d') in the second position which is absent in Dexycu. The prefixes ('Uden' vs. 'Dex') of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair have sufficient phonetic differences and Udenyca has an additional syllable. (b) (4)
3.	Aldex Ct	57	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Dexycu **Established name:** dexamethasone **Dosage form:** suspension for intraocular injection **Strength(s):** 9% **Usual Dose:** Inject 5 mcL into the (b) (4) behind the iris immediately after the completion of surgery	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
4.	Excof	56	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)-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
5.	(b) (4)	57	(b) (4)

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.	Nexcede	64
7.	Ex Dec	60
8.	Excede	56
9.	Exetuss	56
10.	Nexvue	56
11.	Xedec	55

[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

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences

No.	Name
1.	Acne Mask
2.	ACUMOIST With SPF 15
3.	Amphenol-40
4.	Antimonium Tartaricum
5.	Apis Mellifica
6.	Arnica Montana
7.	Arnica Montana (Whole Plant)
8.	Arnicare Arnica
9.	Austedo
10.	Avedana Pain-Relieving
11.	Bacteriostatic Sodium Chloride
12.	Barcroft Visco-9
13.	Benzoyl Peroxide
14.	Bpo 9 Foaming
15.	Brace Relief
16.	Budesonide
17.	By Pharmicell Lab Beaucell Dual Hydrogel Mask
18.	Carbo Vegetabilis
19.	Cheiranthus Cheiri
20.	Codeinum
21.	Covergirl Aquasmooth
22.	Egg
23.	Emsam
24.	Femur 9 Special Order
25.	Graphite
26.	Hanskin Hyaluron Skin Essence
27.	Hepar Sulphuris Calcareum

No.	Name
28.	Intense Care Snail
29.	Invega
30.	Lachesis Mutus
31.	Loesch HC-10 ANTI-ITCH THERAPY
32.	Lycopodium Clavatum
33.	Medihaler-Ergotamine
34.	Minitran
35.	Morphinum
36.	Motto
37.	Myogesic-Cs
38.	Na a Forte X
39.	Natroba
40.	Naturalth Goat Milk Moisture
41.	Neti Wash Flu
42.	Neutral Sodium Fluoride
43.	Nitroglycerin
44.	Nitroglycerin Slocaps
45.	Nitro-Time
46.	Obeo Hair
47.	Oral-B Neutra-Foam Mint
48.	Paliperidone
49.	Pamidronate Disodium
50.	Pleo Poly E
51.	Pleo Poly M
52.	Premium Natural BL Hydrogel Mask Pack
53.	Radium Bromatum
54.	Scrub Care Pvip Surgical Scrub Brush
55.	Sepia Officinalis

No.	Name
56.	Shaving Factory
57.	Silicea
58.	Snail
59.	Sodium Chloride
60.	Spinosad
61.	Symphytum Officinale
62.	Topmax
63.	Uceris
64.	Veterinary Sodium Chloride
65.	Vetivex
66.	Xtampza

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/s/

SHERLY ABRAHAM
07/18/2017

SARAH K VEE
07/18/2017

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 14, 2016
Application Type and Number:	IND 105562
Product Name and Strength:	Dexycu (Dexamethasone) Suspension for Intraocular Injection, 9% 517 mg/0.005 mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Icon Bioscience
Panorama #:	2015-1594704
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Dexycu, 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 PRODUCT INFORMATION

The following product information is provided in the September 24, 2015 proprietary name submission.

- Intended Pronunciation: dex' y kue
- Active Ingredient: Dexamethasone
- Indication of Use: [redacted] (b) (4) for the treatment of postoperative inflammation
- Route of Administration:
- Dosage Form: Suspension for Intraocular Injection
- Strength: 9%
- Dose and Frequency: Inject 5 µL into the [redacted] (b) (4) behind the iris immediately after the completion of surgery
- How Supplied: Each kit contains a single-use 2-cc glass vial with a blue cap designed to deliver 5 µL of 103.4 mg/mL dexamethasone
- Storage: Store at [redacted] (b) (4) Container and Closure Systems:

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. DMEPA concurred with the findings of OPDP's assessment of the proposed name. The Division of Ophthalmology Products (DTOP) found the name promotional; please see the discussion in Section 2.2.4.

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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Dexycu in their submission. This proprietary name is comprised of a single 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

Seventy-eight practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 2, 2015, e-mail, the Division of Transplant and Ophthalmology Products (DTOP) stated that they object to the proposed name Dexycu because it is very similar to "Dexy-see-you". DTOP noted that this product will treat inflammation and will not directly affect vision despite its use in conjunction with cataract surgery. The name's similarity to "Dexy See You" implies a direct effect on vision, and thus they believe the name is promotional and misleading. This concern was shared with OPDP. OPDP re-reviewed the name taking into account DTOP's concern and maintained their non-objection to the name after re-evaluation. DMEPA concurs with OPDP's assessment.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	83
Low similarity name pair: combined match percentage score ≤49%	1

[1]USAN stem search conducted on January 26, 2016.

[2] POCA search conducted on October 21, 2015.

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Dexycu will be available in strength of 9%. Since this is not a typical strength that is not commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Dexycu that were not identified in POCA, and found to have an overlap in strength with Dexycu.

Table 1A. eDRLS Search Results	**POCA score**
N/A	

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

Our analysis of the 85 names contained in Table 1 determined 85 names will not 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 Transplant and Ophthalmology Products (DTOP) via e-mail on February 17, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DTOP on February 18, 2016, they noted that they have no other concerns with the name besides the promotional concerns they had noted previously. As outlined in section 2.2.4, DTOP's concerns were shared with OPDP and upon re-review OPDP maintained their non-objection to the name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Dexycu should be submitted once the NDA is submitted.

If any of the proposed product characteristics as stated in your September 24, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

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. [3]

[3] 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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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 ≥50% 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Dexycu Study (Conducted on 10-23-2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Dexycu 5uL into (b) (4) behind the iris Outpatient Prescription: 	Dexycu Use as directed #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
78 People Responded

Study Name: Dexycu

Total	29	26	23	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DESYCU	1	0	0	1
DEXE Q	0	1	0	1
DEXEQU	0	1	0	1
DEXGEN	1	0	0	1
DEXI Q	0	2	0	2
DEXICUE	0	4	0	4
DEXIQ	0	1	0	1
DEXI-Q	0	1	0	1

DEXIQU	0	2	0	2
DEXIQUE	0	13	0	13
DEXIYEW	0	0	1	1
DEXYAR	0	0	1	1
DEXYAU	0	0	1	1
DEXYAW	0	0	1	1
DEXYCIN	1	0	1	2
DEXYCIO	1	0	0	1
DEXYCIR	1	0	0	1
DEXYCIRE	1	0	0	1
DEXYCO	0	0	2	2
DEXYCU	14	0	7	21
DEXYCW	0	0	3	3
DEXYEN	2	0	0	2
DEXYEU	0	0	1	1
DEXYEW	5	0	5	10
DEXYGEN	1	0	0	1
DEXYLUO	1	0	0	1
DEZIQUE	0	1	0	1

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

No.	**Proposed name:** Dexycu **Established name:** Dexamethasone **Dosage form:** Suspension for Intraocular Injection **Strength(s):** 9% **Usual Dose:** Inject 5 µL into the (b) (4) behind the iris immediately after the completion of surgery	**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.	DEXYCU	100	Subject of this review

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	DOXY-D (Phonetic Score: 70)	64
2.	VIDEX EC	60
3.	DOXY 100	60
4.	DOXY 200	60
5.	DEXONE 0.5	58
6.	DEXONE 0.75	58
7.	DEXONE 1.5	58
8.	DEXONE 4	58
9.	DEX4	56
10.	QUDEXY	54
11.	DILEX-G	52
12.	DILTZAC	51
13.	DEXTRAN 40	51
14.	DEXTRAN 75	51
15.	DOXEPIN	50

No.	Name	POCA Score (%)
16.	DOCUSATE	50
17.	DOXIL	50
18.	DESCOVY***	50
19.	QUDEXY XR	50
20.	DESQUAM	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Dexycu **Established name:** Dexamethasone **Dosage form:** Suspension for Intraocular Injection **Strength(s):** 9% **Usual Dose:** Inject 5 µL into the (b) (4) behind the iris immediately after the completion of surgery	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	DEX-TUSS (Phonetic Score: 76)	68	The infixes of this name pair have sufficient orthographic differences. The Dexycu name contains an extra syllable.
2.	DEXACEN-4	62	The suffixes of this name pair have sufficient orthographic differences. The Dexacen-4 name contains an extra syllable.
3.	DEXASOL	58	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
4.	DESPEC	58	The suffixes of this name pair have sufficient orthographic differences. The Dexycu name contains an extra syllable.
5.	DUEXIS	57	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
6.	DEXACINE	57	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
7.	DEPOCYT	56	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.

No.	**Proposed name:** Dexycu **Established name:** Dexamethasone **Dosage form:** Suspension for Intraocular Injection **Strength(s):** 9% **Usual Dose:** Inject 5 µL into the (b) (4) behind the iris immediately after the completion of surgery	**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**
8.	DEXAIR	56	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
9.	DECOFED	54	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
10.	DESOXYN	54	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
11.	DATSCAN	52	The infixes of this name pair have sufficient orthographic differences. The Datscan name contains an extra syllable.
12.	DEXTRAN	51	The suffixes of this name pair have sufficient orthographic differences. The Dexycu name contains an extra syllable.
13.	DEXTRAN 70	51	The suffixes of this name pair have sufficient orthographic differences. The Dextran 70 name contains an extra syllable.
14.	DOXIDAN	50	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
15.	DEXOPHED	50	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.

No.	**Proposed name:** Dexycu **Established name:** Dexamethasone **Dosage form:** Suspension for Intraocular Injection **Strength(s):** 9% **Usual Dose:** Inject 5 µL into the (b) (4) behind the iris immediately after the completion of surgery	**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**
16.	(b) (4)	50	The suffixes of this name pair have sufficient orthographic differences. The Dexycu name contains an extra syllable.
17.	DEPACON	50	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
18.	DEXFERRUM	50	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
19.	DEXACIDIN	50	The infixes of this name pair have sufficient orthographic differences. The Dexacidin name contains an extra syllable.
20.	DOCU	50	The infixes of this name pair have sufficient orthographic differences. The Dexycu name contains an extra syllable.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Dextenza	46

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	DEX PC	68	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
2.	DOXYCHEL (Phonetic Score: 72)	66	This name was identified by the Drugs at FDA. However, the Brand is discontinued with no generic equivalent available. ANDA 061720 was withdrawn FR effective 2/2/2001.
3.	DEXIUM	68	This name was identified by the RxNorm database. However, this product is listed as an international product marketed in Germany.
4.	DEXACORT	61	This name was identified by the Drugs at FDA. However, the Brand is discontinued with no generic equivalent available. NDA 013413 was withdrawn FR effective 6/16/2006.
5.	(b) (4) ***	60	This name was identified by the Name Entered by Safety Evaluator. However, this name was found unacceptable in OSE #s 06-0107 and 06-0107. ANDA 40700 was approved as dexamethasone.

No.	Name	POCA Score (%)	Failure preventions
6.	DOXY-CAPS	60	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
7.	DOXY	60	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
8.	DAXAS***	58	This name was identified by the Name Entered by Safety Evaluator. However, this name was found unacceptable in OSE # 2010-2038. NDA 22522 was approved as Daliresp.
9.	DECAVAC	58	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
10.	DEXONE	58	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
11.	DESPEC CR	56	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
12.	TROXYCA***	55	This name was identified by the Name Entered by Safety Evaluator. However, this name was deemed unacceptable in OSE # 2013-414 and 2013-1855. IND (b) (4) is active.
13.	DOXYCLINE	55	This name was identified by the RxNorm database. However, this product is listed as an international product marketed in Thailand.
14.	DROXICAM	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
15.	DEXOL	54	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
16.	(b) (4) (Phonetic Score: 76)	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
17.	DILEX-G 200	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

No.	Name	POCA Score (%)	Failure preventions
18.	DOXYTEX	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
19.	DEX-TUSS DM	52	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
20.	DEXAJECT	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
21.	DIOCTO-C	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
22.	DIOCTO-K	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
23.	(b) (4) ***	51	This name was identified by the Name Entered by Safety Evaluator. However, this name was deemed unacceptable in OSE # 2012-478. ANDA 65287 was approved in the nonproprietary name doxycycline hyclate.
24.	ZOXYCIL	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
25.	DEXATRIM	51	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.
26.	DEXTRAN 1	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
27.	DEXTRAN 110	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
28.	DOXATET	50	This name was identified by the RxNorm database. However, this product is listed as an international product marketed in United Kingdom.
29.	DIXARIT	50	This name was identified by the RxNorm database. However, this product is listed as an international product marketed in Canada.
30.	DETUSSIN	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	(b) (4)***	54
2.	NEXIUM	54
3.	EVOXAC	52
4.	LEXPEC	52
5.	NEXICLON	52
6.	TEXACORT	52
7.	APEXICON	50
8.	EXETUSS	50
9.	MAXIFLU	50
10.	MEXATE	50

No.	Name	POCA Score (%)
11.	STAXYN	50
12.	VECTICAL	50
13.	(b) (4) ***	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	ANTIMONIUM TARTARICUM
2.	APIS MELLIFICA
3.	ARNICA MONTANA
4.	ARNICA MONTANA (WHOLE PLANT)
5.	Arnicare Arnica
6.	Avedana Pain-Relieving
7.	Bacteriastatic Sodium Chloride
8.	Bacteriostatic Sodium Chloride
9.	Bacteriostatic Sodium Chloride
10.	Bacteriostatic Sodium Chloride
11.	BPO 9 Foaming
12.	Brace Relief
13.	By Pharmicell Lab Beaucell Dual Hydrogel Mask
14.	CODEINUM
15.	Covergirl Aquasmooth
16.	EMSAM
17.	Femur 9 Special Order
18.	GRAPHITE
19.	HEPAR SULPHURIS CALCAREUM
20.	Intense Care Snail
21.	INVEGA

No.	Name
22.	LACHESIS MUTUS
23.	Loesch HC-10 ANTI-ITCH THERAPY
24.	LYCOPODIUM CLAVATUM
25.	Minitran
26.	MORPHINUM
27.	Motto
28.	Naja Forte
29.	Natroba
30.	Neti Wash Flu
31.	Nitroglycerin
32.	Nitro-Time
33.	Nitro-Time
34.	NITRO-TIME
35.	Oral-B Neutra-Foam Mint
36.	Paliperidone
37.	Paliperidone
38.	Paliperidone
39.	Pamidronate Disodium
40.	Pamidronate Disodium
41.	Pamidronate Disodium
42.	Pamidronate Disodium
43.	Pamidronate Disodium
44.	Pamidronate Disodium
45.	Pamidronate Disodium
46.	Pamidronate Disodium
47.	Pamidronate Disodium
48.	Pleo Poly E
49.	Pleo Poly M
50.	Premium natural BL hydrogel mask pack

No.	Name
51.	Scrub-In Surgical Scrub Brush/Sponge
52.	SEPIA OFFICINALIS
53.	Shaving Factory
54.	SILICEA
55.	Sodium Chloride
56.	Sodium Chloride
57.	SODIUM CHLORIDE
58.	Sodium Chloride
59.	Sodium Chloride
60.	Sodium Chloride
61.	Sodium Chloride
62.	Sodium Chloride
63.	Sodium Chloride
64.	Sodium Chloride
65.	Sodium Chloride
66.	Sodium Chloride
67.	Sodium Chloride
68.	Sodium Chloride
69.	Sodium Chloride
70.	Sodium Chloride
71.	Sodium Chloride
72.	Sodium Chloride
73.	Sodium Chloride
74.	Sodium Chloride
75.	sodium chloride
76.	Sodium Chloride
77.	Sodium Chloride
78.	Sodium Chloride
79.	Sodium Chloride
80.	Sodium Chloride

No.	Name
81.	Sodium Chloride
82.	Sodium Chloride
83.	Sodium Chloride
84.	Sodium Chloride
85.	Sodium Chloride
86.	Sodium Chloride
87.	Sodium Chloride
88.	Spinosad
89.	Spinosad
90.	SYMPHYTUM OFFICINALE
91.	Uceris

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/s/

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03/14/2016

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03/16/2016