CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208742Orig1s000

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:	September 26, 2018
Application Type and Number:	NDA 208742
Product Name and Strength:	Dextenza (dexamethasone) intracanalicular insert
Total Product Strength:	0.4 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ocular Therapeutix, Inc.
Panorama #:	2018-24331430
DMEPA Safety Evaluator:	Nasim Roosta, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Director	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Dextenza, 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 submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Dextenza, on November 4, 2014, which we found conditionally acceptable (OSE # 2014-42586) under IND 114720[a]. The Applicant re-submitted the name on August 12, 2015 (IND 114720) to include additional indications and November 9, 2015 as part of the NDA submission (NDA 208742). We found the name conditionally acceptable (OSE # 2015-1184867 and 2015-1947601)[b]. However, NDA 208742 received a complete response on July 21, 2016. The Applicant re-submitted the name, Dextenza, for review on January 19, 2017, which was found to be conditionally acceptable (OSE # 2017-12734266)[c]. On July 10, 2017, the Application again received a complete response. With this resubmission, Ocular Therapeutix included a request for proprietary name review of the proposed proprietary name, Dextenza. We note that all product characteristics remain the same from previous submissions.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 3, 2018.

- Intended Pronunciation: Deks-TEN-zah
- Active Ingredient: Dexamethasone
- Indication of Use: corticosteroid indicated for the treatment of ocular pain occurring after ophthalmic surgery.
- Route of Administration: Intracanalicular
- Dosage Form: Sustained-release intracanalicular insert
- Strength: 0.4 mg
- Dose and Frequency: 0.4 mg inserted into the lacrimal canaliculus following ophthalmic surgery. Resorbable and does not require removal

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[a] Rahimi L. Proprietary Name Review for Dextenza (IND 114720). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); [2015 APR 15]. RCM No.: 2014-42586.

[b] Rutledge M. Proprietary Name Review for Dextenza Memorandum (IND 114720 and NDA 208742). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); [2016 APR 15]. RCM NO.: 2015-1184867 and 2015-1947601.

[c] Patel, M. Proprietary Name Review for Dextenza (NDA 208742). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); [2017 APR 12]. RCM No.: 2017-12734266.

- How Supplied: Sterile in a foam carrier within a foil laminate pouch. Carton containing (b) (4) or 10 pouches.
- Storage: Store refrigerated, between 2°C and 8°C (36˚F and 46˚F). Protect from light, keep in package until use
- Container and Closure Systems: One resorbable sterile insert in a foam carrier within a foil laminate pouch

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Transplant and 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[d].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Dextenza 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, July 31, 2018 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Sixty-one (61) 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.

[d] USAN stem search conducted on July 6, 2018.

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

Our POCA search[e] identified 121 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. We had identified and evaluated some of the names in our previous proprietary name reviews. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous reviews for the names evaluated previously. Therefore, we identified eight names not previously analyzed. These names are included in Table 1 below.

2.2.6 *Names Retrieved for Review Organized by Name Pair Similarity*

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	8
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the nine names contained in Table 1 determined that eight of the names will not pose a risk for confusion as described in Appendices C through H. However, the proposed name could be confused with another proposed proprietary name, (b) (4) *** for the reasons described below (see section titled "Dextenza vs. (b) (4) ***. Based on our assessment, we do not object to the proposed proprietary name, Dextenza, at this time.

Dextenza vs. (b) (4) ***

The proposed name, Dextenza, may be confused with (b) (4),

[e] POCA search conducted on July 18, 2018 in version 4.2.

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 September 25, 2018. At that time we also requested additional information or concerns that could inform our review. No comments were forwarded from DTOP regarding the proposed proprietary name, Dextenza.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Azeem Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on July 3, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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. [f]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

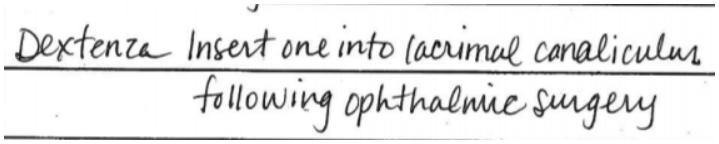
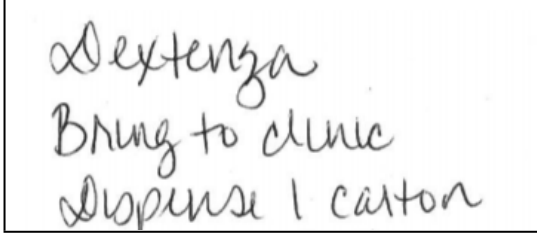
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Dextenza Study (Conducted on July 20, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Dextenza Bring to clinic Dispense one carton
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

308 People Received Study
61 People Responded

Study Name: Dextenza

Total	22	18	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DEXSTENZA	0	2	0	2
DEXTENDSA	0	1	0	1
DEXTENSA	0	1	0	1
DEXTENZ	1	0	0	1
DEXTENZA	21	14	20	55
DEXTNZA	0	0	1	1

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

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 0.4 mg inserted into the lacrimal canaliculus following ophthalmic 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.	Dextenza***	100	Name under 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 (%)
	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:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 0.4 mg inserted into the lacrimal canaliculus following ophthalmic 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.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.
4.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
7.	(b) (4) ***	58	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, (b) (4)
8.	(b) (4) ***	58	Proposed proprietary name (b) (4)

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

No.	Name	POCA Score (%)
	N/A	

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

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

/s/

NASIM N ROOSTA
09/26/2018

OTTO L TOWNSEND
09/26/2018

IRENE Z CHAN
09/27/2018

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

Date of This Review:	April 12, 2017
Application Type and Number:	NDA 208742
Product Name and Strength:	Dextenza (dexamethasone) intracanalicular insert 0.4 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ocular Therapeutix, Inc.
Panorama #:	2017-12734266
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD
DMEPA Team Leader (Acting):	Sarah K. Vee, PharmD

Contents

1 INTRODUCTION

This review re-evaluates the proposed proprietary name, Dextenza, 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 submitted an external name study, conducted by (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Dextenza, on November 4, 2014, along with the same external name study conducted by (b) (4) which Division of Medication Error Prevention and Analysis (DMEPA) found acceptable in OSE review# 2014-42586, IND 114720[a]. The Applicant re-submitted the name again on August 12, 2015 (IND 11470) and November 9, 2015 (NDA 208742), which was found acceptable in OSE review# 2015-1184867 and 2015-1947601[b]. However, NDA 208742 received a complete response on July 21, 2016.

Thus, the applicant re-submitted the name, Dextenza, for review on January 19, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 19, 2017, proprietary name submission.

- Intended Pronunciation: Deks-TEN-zah
- Active Ingredient: Dexamethasone
- Indication of Use: corticosteroid indicated for the treatment of ocular pain occurring after ophthalmic surgery.
- Route of Administration: Intracanalicular
- Dosage Form: Sustained-release intracanalicular insert
- Strength: 0.4 mg
- Dose and Frequency: 0.4 mg inserted into the lacrimal canaliculus following ophthalmic surgery. Resorbable and does not require removal
- How Supplied: Sterile in a foam carrier within a foil laminate pouch. Carton containing (b) (4) or 10 pouches.

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[a] Rahimi L. Proprietary Name Review for Dextenza (IND 114720). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 15. 19 p. OSE RCM NO.: 2014-42586.

[b] Rutledge M. Proprietary Name Review for Dextenza Memorandum (IND 114720 and NDA 208742). 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 Apr 15. 5 p. OSE RCM NO.: 2015-1184867 and 2015-1947601.

- Storage: Store refrigerated, between 2°C and 8°C (36˚F and 46˚F). Protect from light, keep in package until use
- Container and Closure Systems: One resorbable sterile insert in a foam carrier within a foil laminate pouch

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 and the Division of Transplant and 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[c].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Dextenza, 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 FDA Name Simulation Studies

Sixty-four (64) 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, February 9, 2017 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[c] USAN stem search conducted on March 22, 2017.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 104 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated 142 names in our previous proprietary name review using a previous version of POCA[e]. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. However, we identified 8 names in POCA version 4.0 determined to be highly similar name pairs that were previously analyzed and evaluated as moderately similar name pairs based on a previous version of POCA. We also identified 33 names not previously analyzed. These names are included in Table 1 below.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	9
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	24
Low similarity name pair: combined match percentage score ≤54%	8

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

The proposed product, Dextenza will be available in strength of 0.4 mg. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Dextenza that were not identified in POCA.

Table 1A. eDRLS Search Results[f]	**POCA Score (%)**
N/A	N/A

[d] POCA search conducted on March 16, 2017 in version 4.0.

[e] Rahimi L. Proprietary Name Review for Dextenza (IND 114720). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 15. 19 p. OSE RCM NO.: 2014-42586.

[f] eDRLS search conducted on March 22, 2017.

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

Our analysis of the 41 names contained in Table 1 determined 41 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 March 29, 2017. At that time we also requested additional information or concerns that could inform our review. DTOP did not state any additional concerns with the proposed proprietary name, Dextenza.

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, Dextenza, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your January 19, 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. [g]

[g] 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[h]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

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

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	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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

<table>
<tr><td></td><td colspan="2">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</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</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>

	scripted?	

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. Dextenza Study (Conducted on February 15, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Dextenza Insert into lacrimal canaliculus after procedure Outpatient Prescription: Dextenza Bring to clinic Dispense #1	Dextenza Bring to clinic. Dispense #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study
64 People Responded

Study Name: Dextenza

Total	31	18	15	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DESTENZA	0	1	0	1
DEXSENDSA	0	1	0	1
DEXSTENZA	0	1	0	1
DEXTENGA	1	0	0	1
DEXTENYA	2	0	0	2
DEXTENZA	28	15	15	58

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

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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.	(b) (4)		
2.	Dextran	72	The 'r' in the 5th position of Dextran and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable. The middle sounds of the second syllables ('ra' vs. 'e') of this name pair sound different.

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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.**
3.	Dextran 1	72	The 'r' in the 5th position of the Dextran root name and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to Dextran root name. The middle sounds of the second syllables ('ra' vs. 'e') of the root names of this name pair sound different. Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. The brand name, Promit is listed as deactivated per Redbook.
4.	Dextran 110	72	The 'r' in the 5th position of the Dextran root name and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to Dextran root name. The middle sounds of the second syllables ('ra' vs. 'e') of the root names of this name pair sound different. Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. This product was identified in Google as an excipient for final formulation, drug product, for medical devices, for production of solutions for injection and infusion.
5.	Dextran 40	72	The 'r' in the 5th position of the Dextran root name and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to Dextran root name. The middle sounds of the second syllables ('ra' vs. 'e') of the root names of this name pair sound different.

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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.**
6.	Dextran 70	72	The 'r' in the 5th position of the Dextran root name and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to Dextran root name. The middle sounds of the second syllables ('ra' vs. 'e') of the root names of this name pair sound different. Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. The brand name is listed as deactivated per Redbook.
7.	Dextran 75	72	The 'r' in the 5th position of the Dextran root name and the 'za' letter string in the suffix of Dextenza provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to Dextran root name. The middle sounds of the second syllables ('ra' vs. 'e') of the root names of this name pair sound different.
8.	Extina	70	The lengths of the names differ by 2 letters. The first letters ('D' vs. 'E') of this name pair and the letter 'z' in the suffix of Dextenza that is not present in Extina provides sufficient orthographic differences. The first sounds of the first syllables ('D' vs. 'E') and the first sounds of the third syllables ('z' vs. 'a') of this name pair sound different. Dose: 1 insert into lacrimal canaliculus following ophthalmic surgery vs. apply to the affected area(s) twice daily for four weeks or use as directed

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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.**
9.	Hextend	70	The first letters ('D' vs. 'H') and the suffixes ('za' vs. upstroke letter 'd') of this pair have sufficient orthographic differences. Dextenza name contains an extra syllable. The first sounds of the first syllables ('D' vs. 'H') and the last syllables ('za' vs. 'tend') Dose: 1 insert into lacrimal canaliculus following ophthalmic surgery vs. 500-1500 mL or 20 mL per kg of body weight via intravenous infusion

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 (%)
10.	Dextrose 50%	60
11.	Jatenzo***	59

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:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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**
12.	Andexxa***	64	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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**
13.	(b) (4)***	62	The lengths of the names differ by 2 letters. The infixes and suffixes have sufficient orthographic differences. The first and second syllables of this name pair sound different.
14.	Dupixent***	58	The infixes and suffixes have sufficient orthographic differences. The second and third syllables of this name pair sound different.
15.	Aldex An	56	The lengths of the names differ by 2 letters. The additional upstroke letter in the infix for the Aldex root name and the 'nza' letter string in Dextenza provide sufficient orthographic differences. Dextenza name contains an extra syllable when compared to the Aldex An root name. The first and second syllables of the root names of this name pair sound different.
16.	Benzodent	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
17.	Besponsa***	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
18.	Maxidex	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
19.	(b) (4)***	56	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name:** Dextenza **Established name:** Dexamethasone **Dosage form:** Sustained-release intracanalicular insert **Strength(s):** 0.4 mg **Usual Dose:** 1 insert into lacrimal canaliculus following ophthalmic 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**
20.	Diet X-Strength	55	The lengths of the root names differ by 4 letters. The 'enza' letter string that is not present in the root name for Diet X-Strength provides sufficient orthographic differences. Dextenza name contains an extra syllable when compared to the Diet X-Strength root name. The last sounds of the first syllables ('ex' vs. 'i') and second syllables of the root names of this name pair sound different.

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

No.	Name	POCA Score (%)
21.	Dimetane Extentab	54
22.	Exna	54
23.	Zaditen	54
24.	Detane	52
25.	Tadenan	52
26.	Anndexa***	50
27.	Ethenzamide	48
28.	Tena	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
29.	Nexphen Pd	64	Discontinued guaifenesin/phenylephrine hydrochloride product with no generic equivalents available.
30.	Canesten Af	56	International product formerly marketed in United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
31.	Extendryl G	56	Discontinued guaifenesin/phenylephrine hydrochloride product with no generic equivalents available.

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

No.	Name	POCA Score (%)
32.	Mentadent	59
33.	Maxtrex	58
34.	Mexate-Aq	58
35.	Nexafed	58
36.	Zeaxanthin	57
37.	Exenatide	56
38.	Nexgard	56
39.	Noxivent***	56
40.	Nexplanon	55
41.	Xeljanz	55

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

No.	Name
42.	Dr. Scholls
43.	Dr. Scholls Duragel Callus Removers
44.	Diaper Rash

[i] 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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/s/

MADHURI R PATEL
04/12/2017

SARAH K VEE
04/12/2017

PROPRIETARY NAME MEMORANDUM

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:	January 19, 2016
Application Type and Number:	IND 114720 NDA 208742
Product Name and Strength:	Dextenza (Dexamethasone) Punctum Plug 0.4 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ocular Therapeutix, Inc.
Panorama #:	2015-1184867 2015-1947601
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Dextenza under IND 114720 and NDA 208742, which was found acceptable in a previous OSE review# 2014-42586, IND 114720[1].

1.1 PRODUCT INFORMATION

The following product information is provided in the August 12, 2015 (IND 11470) and November 9, 2015 (NDA 208742) proprietary name submissions.

- Intended Pronunciation: Deks-TEN-zah
- Active Ingredient: Dexamethasone
- Indication of Use:

IND 11470	NDA 208742
• Treatment of ocular pain and inflammation associated with ophthalmic surgery (b) (4)	• Treatment of ocular pain and inflammation associated with ophthalmic surgery

- Route of Administration: Intra-ocular insert
- Dosage Form: Single Punctum Plug
- Strength: Approximately 0.4 mg dexamethasone
- Dose and Frequency: Single Plug, One time
- How Supplied: Single plug in a foil pouch
- Storage: Refrigerated, between 2°C and 8°C
- Container and Closure Systems: One resorbable hydrogel puntum plug in foam carrier in (b) (4) pouch

2 METHODS AND DISCUSSION

[1] Rahimi L. Proprietary Name Review for Dextenxa (IND 114720). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 15. 19 p. OSE RCM NO.: 2014-42586.

To re-assess the proposed proprietary name, the Division of Medication Error Prevention and Analysis (DMEPA) searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 12, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Because we recently reviewed the name Dextenza and we note the only change is the (b) (4) we maintain that the name is acceptable.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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, Dextenza, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your August 12, 2015 and November 9, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. Rahimi L. Proprietary Name Review for Dextenxa (IND 114720). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 15. 19 p. OSE RCM NO.: 2014-42586.

2. 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.

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/s/

MICHELLE K RUTLEDGE
01/19/2016

YELENA L MASLOV
01/21/2016