CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208193Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 23, 2019
Application Type and Number:	NDA 208193
Product Name and Strength:	Ozobax (baclofen) Oral Solution, 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Metacel Pharmaceuticals, LLC (Metacel)
Panorama #:	2019-30148806
DMEPA Safety Evaluator:	Colleen Little, PharmD
DMEPA Team Leader (Acting):	Briana Rider, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ozobax, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Metacel submitted an external name study, conducted (b) (4) for this proposed proprietary name; which was evaluated in a previous review.[a]

1.1 REGULATORY HISTORY

Metacel previously submitted the proposed proprietary name, Ozobax on January 9, 2016 under NDA 208193. We found the name conditionally acceptable on April 1, 2016.[b] However, NDA 208193 received a Complete Response on January 11, 2017.

On January 1, 2018, Metacel re-submitted the proposed proprietary name, Ozobax, for review as part of the resubmission under NDA 208193. We found the name conditionally acceptable on March 27, 2018.[a] However, NDA 208193 received a Complete Response on June 25, 2018.

Thus, upon resubmission of NDA 208193, Metacel submitted the name, Ozobax, for review on March 18, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 18, 2019.

- Intended Pronunciation: not provided
- Active Ingredient: baclofen
- Indication of Use: (b) (4) spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. (b) (4) Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
- Route of Administration: Oral
- Dosage Form: Oral Solution
- Strength: (b) (4)
- Dose and Frequency: (b) (4)

[a] Rider, B. Proprietary Name Review for Ozobax (NDA 208193). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAR 27. Panorama No. 2018-20074116.

[b] Harris, J. Proprietary Name Review for Ozobax (NDA 208193). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 APR 01. Panorama No. 2016-2493019.

[redacted] (b) (4)

- 5 mL (5 mg) three times a day for three days
- 10 mL (10 mg) three times a day for three days
- 15 mL (15 mg) three times a day for three days
- 20 mL (20 mg) three times a day for three days

[redacted] (b) (4)

- How Supplied: Bottles of 473 mL
- Storage: Store at 2°C to 8°C (36°F to 46°F). [redacted] (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Ozobax would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment for Ozobax.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Metacel did not provide a derivation or intended meaning for the proposed proprietary name, Ozobax, 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, April 1, 2019 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to Ozobax at the initial phase of the review.

[c] USAN stem search conducted on March 22, 2019.

2.2.4 FDA Name Simulation Studies

Fifty-eight practitioners participated in DMEPA's prescription studies for Ozobax. 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[d] identified 127 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name 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 2 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. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

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

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

Our analysis of the 2 names contained in Table 1 determined none of the names will pose a risk for confusion with Ozobax 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 Neurology Products (DNP) via e-mail on April 12, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP)

[d] POCA search conducted on March 22, 2019 in version 4.3.

on April 23, 2019, they stated no additional concerns with the proposed proprietary name, Ozobax.

3 CONCLUSION

The proposed proprietary name, Ozobax, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO METACEL PHARMACEUTICALS, LLC

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

If any of the proposed product characteristics as stated in your submission, received on March 18, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

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

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

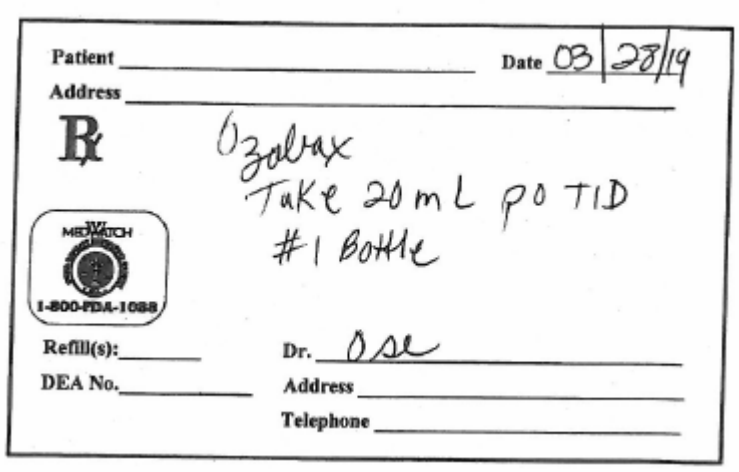
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Ozobax Study (Conducted on March 29, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Ozobax 5ml po TID x 3 days Outpatient Prescription:  Patient _____ Date 03/28/19 Address _____ ℞ Ozobax Take 20 mL po TID #1 Bottle MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. Ose DEA No._____ Address _____ Telephone _____	Ozobax Take 20 mL by mouth three times daily Dispense # 1 bottle

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Ozobax

As of Date 4/8/2019

221 People Received Study

58 People Responded

Study Name: Ozobax

Total	30	10	18	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
HOSOBAX	0	1	0	1
OSOBAX	0	1	0	1
OZABAX	6	0	0	6
OZALAX	3	0	0	3
OZALRAX	1	0	0	1
OZDRAX	0	0	1	1
OZOBAX	16	7	17	40
OZOLAX	4	0	0	4
OZOPAX	0	1	0	1

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

No.	**Proposed name:** Ozobax **Established name:** baclofen **Dosage form:** Oral Solution **Strength(s):** (b) (4) **Usual Dose:** Titration doses range from 5 mg to 20 mg three times daily. Maximum daily dose: 80 mg	**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.**
	N/A		

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:** Ozobax **Established name:** baclofen **Dosage form:** Oral Solution **Strength(s):** (b) (4) **Usual Dose:** Titration doses range from 5 mg to 20 mg three times daily. Maximum daily dose: 80 mg	**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**
	N/A		

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
1.	Posatex	56	Veterinary product.
2.	Semax	53 (P:70)	International product formerly marketed in Chile.

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 (%)
	N/A	

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

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/s/

COLLEEN L LITTLE
04/23/2019 11:49:29 AM

BRIANA B RIDER
04/23/2019 12:08:28 PM

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 27, 2018
Application Type and Number:	NDA 208193
Product Name and Strength:	Ozobax (baclofen) oral solution 1 mg/ mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Metacel Pharmaceuticals, LLC
Panorama #:	2018-20074116
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ozobax, 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 (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Ozobax, for baclofen oral solution 1 mg/mL, on January 9, 2016, under NDA 208193. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Ozobax, conditionally acceptable on April 1, 2016.[a] However, NDA 208193 received a Complete Response on January 11, 2017.

Thus, the Applicant resubmitted the name, Ozobax, for review upon their Class 2 resubmission of NDA 208193 on January 2, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 2, 2018.

- Intended Pronunciation: none provided
- Active Ingredient: baclofen
- Indication of Use: (b) (4) spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. (b) (4) Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
- Route of Administration: Oral
- Dosage Form: Solution
- Strength: (b) (4)
- Dose and Frequency: (b) (4)
    - 5 mL (5 mg) three times a day for three days
    - 10 mL (10 mg) three times a day for three days
    - 15 mL (15 mg) three times a day for three days
    - 20 mL (20 mg) three times a day for three days

[a] Harris, J. Proprietary Name Review for Ozobax (NDA 208193). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 APR 01. Panorama No. 2016-2493019.

[redacted] (b) (4)

- How Supplied: Bottles of 473 mL
- Storage: Store at 20°C to 25°C (68°F to 77°F). [redacted] (b) (4)

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 Neurology Products (DNP) 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, Ozobax 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 17, 2018 e-mail, the Division of Neurology Products (DNP) 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

Eighty-four practitioners participated in DMEPA's prescription studies. The responses did not directly overlap with any currently marketed products or any products in the pipeline.

One respondent in the outpatient study interpreted the proposed proprietary name as "Ozoloax", which is a close hit to the marketed product, Zoladex. We evaluated the name pair, Ozobax and Zoladex, further and find that there are sufficient orthographic and phonetic differences between the name pair. Orthographically, the letter strings at the beginning of this name pair (Ozo- versus Zola-) are sufficiently different. Also, Zoladex has two upstroke letters 'l' and 'd', whereas

[b] USAN stem search conducted on January 23, 2018.

Ozobax contains one upstroke letter 'b'. Phonetically, the second syllable "zo" in Ozobax sounds different from the second syllable "la" in Zoladex. Additionally, there is no overlap in strength (1 mg/mL versus 3.6 mg and 10.8 mg) or dose (5 mg to 80 mg versus 3.6 mg or 10.8 mg). Thus, we find there is minimal risk of name confusion for this name pair (see Appendix D).

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 123 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated 201 names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 22 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 FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	21
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 28 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on March 23, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on March 27, 2018, they stated no additional concerns with the proposed proprietary name, Ozobax.

[c] POCA search conducted on January 23, 2018 in version 4.2.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on January 2, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

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

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

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

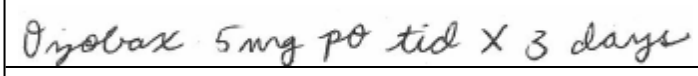
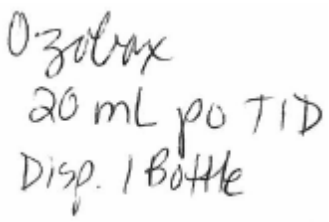
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Ozobax Study (Conducted on January 19, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	"Ozobax Take 20 mL by mouth three times a day. Dispense one bottle"
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

296 People Received Study
84 People Responded

Study Name: Ozobax

Total	31	29	24	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ONJOBAX	0	0	1	1
ORJOBAX	0	0	1	1
OSOBAX	1	2	0	3
OYOBAX	0	0	2	2
OYOBOX	0	0	1	1
OZOBACH	0	1	0	1
OZOBACKS	0	1	0	1
OZOBAKS	0	1	0	1
OZOBAX	16	18	19	53
OZOBOX	8	0	0	8

OZOLAX	4	0	0	4
OZOLOAX	1	0	0	1
OZOVAC	0	1	0	1
OZOVAX	1	4	0	5
OZOVEX	0	1	0	1

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

No.	**Proposed name:** Ozobax **Established name:** baclofen **Dosage form:** oral solution **Strength(s):** (b) (4) **Usual Dose:** Titration doses range from 5 mg tid to 20 mg tid. Maximum daily dose: 80 mg	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.	Ozobax	100	Subject of this review.
2.	Orbax	76	Veterinary product.
3.	Otomax	76	Veterinary product.
4.	Zobuxa	76	Veterinary product.
5.	Probax	70	Name identified in RxNorm database. Deactivated brand of propolis oromucosal gel and propolis 2% topical ointment with no generic equivalent available.
6.	Ziba-Rx	70	ANDA 061737 withdrawn FR effective 12/07/2007.

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

No.	Name	POCA Score (%)
7.	Zoladex	64

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

No.	**Proposed name:** Ozobax **Established name:** baclofen **Dosage form:** oral solution **Strength(s):** (b) (4) **Usual Dose:** Titration doses range from 5 mg tid to 20 mg tid. Maximum daily dose: 80 mg	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.	Dodex	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Ozobax **Established name:** baclofen **Dosage form:** oral solution **Strength(s):** (b) (4) **Usual Dose:** Titration doses range from 5 mg tid to 20 mg tid. Maximum daily dose: 80 mg	**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**
9.	(b) (4)***	56	When comparing the name Ozobax to the root name (b) (4) this name pair has sufficient orthographic and phonetic differences. Ozobax versus the root name (b) (4)*** (b) (4)
10.	Nobac	55	This name pair has sufficient orthographic and phonetic differences.
11.	Tazobactam	55	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
12.	Forbaxin	55	ANDA 085136 withdrawn FR effective 09/25/1998.
13.	Lobac	55	Name identified in Rx Norm. Brand deactivated with no generic equivalents available.
14.	(b) (4)***	54	Proposed proprietary name for BLA #761066 found unacceptable by DMEPA (OSE# (b) (4)). The Sponsor subsequently submitted the proposed proprietary name, (b) (4)*** and this name was also found to be unacceptable by DMEPA (OSE# (b) (4)). BLA 761066 is pending.

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

No.	Name	POCA Score (%)
15.	Botox	64
16.	Zovirax	63
17.	Fosamax	62
18.	Zyvox	62
19.	Flomax	61
20.	Tobrex	61
21.	Cormax	59
22.	Nuromax	58
23.	Tobradex	58
24.	Ziox	58
25.	Pazol Xs	57
26.	Amidox	56
27.	Sonorx	56
28.	Lovenox	55

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

No.	Name

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

No.	Name
1.	N/A

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BRIANA B RIDER
03/27/2018

LOLITA G WHITE
03/27/2018

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)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	April 1, 2016
Application Type and Number:	NDA 208193
Product Name and Strength:	Ozobax (baclofen) Oral Solution 1 mg/ml
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Metacel Pharmaceuticals, LLC
Panorama #:	2016-2493019
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ozobax, 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 [redacted] (b) (4) for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the January 9, 2016 proprietary name submission.

- Intended Pronunciation: none provided
- Active Ingredient: baclofen
- Indication of Use: [redacted] (b) (4) spasticity resulting from multiple sclerosis; may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
- Route of Administration: oral
- Dosage Form: oral solution
- Strength: [redacted] (b) (4)
- Dose and Frequency: [redacted] (b) (4)
  - 5 mg three times daily for 3 days
  - 10 mg three times daily for 3 days
  - 15 mg three times daily for 3 days
  - 20 mg three times daily for 3 days

  [redacted] (b) (4)
- How Supplied: Bottles of 473 mL
- Storage: [redacted] (b) (4)
- Container and Closure Systems: 16 ounce round amber container white [redacted] (b) (4) child resistant cap with induction seal and foil liner

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 Neurology Products (DNP) 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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Ozobax 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 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, January 19, 2016 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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 also includes names identified from the by DSI.

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[1]USAN stem search conducted on January 19, 2016.

[2] POCA search conducted on January 19, 2016.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	194
Low similarity name pair: combined match percentage score ≤49%	4

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

Our analysis of the 201 names contained in Table 1 determined no names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on March 28, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on March 31, 2016, they stated no additional concerns with the proposed proprietary name, Ozobax.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-496-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 9, 2016 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. [3]

***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

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

	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?	**Y/N**	Do the names have different syllabic stresses?

	*****_FDA considers the length of names different if the names differ by two or more letters._		
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.

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

	names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

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. Ozobax Study (Conducted on January 22, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Ozobax 15mg three times daily x 3 days then increase to 20mg three times daily	Ozobax 20 mL three times daily Disp: 1 bottle
Outpatient Prescription: Ozobax 20 mL three times daily Disp: 1 bottle	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

239 People Received Study
63 People Responded

Study Name: Ozobax

Total	9	10	17	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
OSOVAC	0	**1**	0	1
OSZABAX	0	**1**	0	1
OZABAC	0	**2**	0	2
OZABACH	0	**2**	0	2
OZABACS	0	**1**	0	1
OZABAX	0	**1**	1	2
OZABOX	0	**0**	1	1
OZAVAX	0	**2**	0	2
OZEBOX	0	**0**	1	1
OZELOX	0	**0**	1	1
OZOBAC	0	**1**	0	1
OZOBACK	0	**1**	0	1
OZOBAT	0	**1**	0	1
OZOBAX	21	**3**	9	33
OZOBAX15 MG	0	**0**	1	1
OZOBECK	0	**1**	0	1
OZOBOX	0	**0**	3	3
OZOLAX	0	**0**	2	2
OZOVAC	0	**1**	0	1
OZOVAX	3	**2**	0	5

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

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Ozobax	100	Subject of this review
2.	Otomax	78	Veterinary product
3.	Orbax	76	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases

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.	Doribax	63
2.	Inomax	64
3.	Obenix	65
4.	Ocu-Dex	61
5.	Ona-Mast	50
6.	Osmolex	60
7.	Povidex	54
8.	Avonex	62
9.	Cedax	53
10.	Dovonex	60
11.	Efudex	52

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: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Ozurdex	65	The infixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different
2.	Clobex	61	The prefixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different and Ozobax name contains and extra syllable
3.	Alodox	60	The prefixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different
4.	Altabax	56	The prefixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different
5.	Apetex	50	The prefixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Ocudox	64	The prefixes of this name pair have sufficient orthographic differences The first and second syllables and third syllables of this name pair sound different
7.	Imovax	61	The prefixes and suffixes of this name pair have sufficient orthographic differences The first syllables syllables of this name pair sound different
8.	Robaxin	54	The prefixes and suffixes of this name pair have sufficient orthographic differences The first, second and third syllables of this name pair sound different
9.	Robaxin-750	54	The prefixes and suffixes of this name pair (root name Robaxin vs Ozobax) have sufficient orthographic differences The first and third syllables of this name pair (root name Robaxin vs Ozobax) sound different

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s): (b) (4)** **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
10.	Azelex	53	The first and third syllables of this name pair sound different Product Characteristics: The products come in different dosage forms (cream vs. oral solution) , different routes of administration,(topical vs. oral), and different dosing frequencies (twice daily vs three to four times daily) which do not overlap.
11.	Utimox	51	The prefixes and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
12.	Xanax	53	The prefixes and suffixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different and Ozobax name contains an extra syllable
13.	Zerbaxa	57	The prefixes of this name pair have sufficient orthographic differences The first, second and third syllables of this name pair sound different

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
14.	Mozobil	52	The prefixes and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
15.	Ocuflox	51	The prefixes and infixes of this name pair have sufficient orthographic differences The first syllables and third syllables of this name pair sound different
16.	Ontepix	52	The prefixes and suffixes of this name pair have sufficient orthographic differences The first, second and third syllables of this name pair sound different
17.	Sebex	58	The prefixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different and the name Ozobax contains an extra syllable
18.	Oraqix	57	The prefixes and suffixes of this name pair have sufficient orthographic differences The first syllables and third syllables of this name pair sound different

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
19.	Orlex	51	The prefixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different and the name Ozobax contains an extra syllable
20.	Otomax Hc	56	The prefixes and infixes of this name pair (root name Otomax vs Ozobax) have sufficient orthographic differences The first syllables and third syllables of this name pair (root name Otomax vs Ozobax) sound different. The modifier 'HC', if written, provides further differentiation.
21.	Ela-Max	54	The prefixes of this name pair (Ela-max vs Ozobax) have sufficient orthographic differences The first syllables of this name pair (Ela-max vs Ozobax) sound different.
22.	Ela-Max 5	54	The prefixes of this name pair (root name Ela-max vs Ozobax) have sufficient orthographic differences The first syllables of this name pair (root name Ela-max vs Ozobax) sound different. The modifier '5', if written, provides further differentiation

No.	**Proposed name: Ozobax** **Established name: baclofen** **Dosage form: oral solution** **Strength(s):** (b) (4) **Usual Dose: Suggested dosage titration schedule:** **• 5 mg three times daily for 3 days** **• 10 mg three times daily for 3 days** **• 15 mg three times daily for 3 days** **• 20 mg three times daily for 3 days** **not to exceed maximum of 80 mg per day (20 mg four times daily)**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
23.	Zotex C	58	The prefixes and suffixes of this name pair (root name Zotex vs Ozobax) have sufficient orthographic differences The first syllables and second syllables of this name pair sound different. The modifier 'C' , if written, provides further differentiation
24.	Zotex-D	58	The prefixes and suffixes of this name pair pair (root name Zotex vs Ozobax) have sufficient orthographic differences The first syllables and second syllables of this name pair sound different. The modifier 'D' , if written, provides further differentiation

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

No.	Name	POCA Score (%)
1.	Uni-Tex	48
2.	Unit-Tex	46
3.	Videx	47
4.	Azdone	35

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.	Adifax	53	International product formerly marketed in numerous foreign countries
2.	(b) (4) ***	60	Proposed proprietary name found unacceptable in DMEPA review OSE (b) (4); application withdrawn as of Nov 6, 2014.
3.	Alunex	52	International product formerly marketed in the UK.
4.	Anabact	50	International product marketed in UK.
5.	Animax	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	50	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Quillivant XR.

No.	Name	POCA Score (%)	Failure preventions
7.	Duomax	60	International product marketed in Philippines (as rifampin isoniazid); this formulation (guiafenesin/phenylephrine) is no longer available in US: deactivated per Redbook
8.	Evitex	50	International product marketed in Italy and Israel
9.	E-Z Mix	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	(b) (4) ***	51	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases..
11.	Isovex	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases; deactivated per Redbook
12.	Je-Vax	54	Deactivated per Redbook; no generics available
13.	Jojoba Wax	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
14.	Jomax	65	International product formerly marketed in Germany
15.	Optimax	58	Deactivated per RedBook and no generics available

No.	Name	POCA Score (%)	Failure preventions
16.	Orbexa	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
17.	Orelox	56	Foreign drug marketed in multiple countries (Germany, Brazil, France, Italy,Mexico, South Africa, Swizerland, Turkey)
18.	Ornex	56	Deactivated per RedBook and no generics available
19.	(b) (4) ***	54	Name withdrawn by sponsor; alternate name Osmolex submitted for review
20.	Osmoflex	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
21.	Ostilox	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
22.	Otex	52	Foreign drug marketed in United Kingdom
23.	Ovaban	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
24.	Probax	66	Deactivated per Redbook; no generics available
25.	(b) (4) ***	60	This is a secondary proposed proprietary name and the product was approved under proprietary name Sivextro

No.	Name	POCA Score (%)	Failure preventions
26.	Robadex	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
27.	Rubex	54	Deactivated per Redbook; no generics available
28.	Stomax	60	Deactivated per Redbook; no generics available
29.	Sudex	50	Deactivated per Redbook; no generics available
30.	Urimax	56	Deactivated per Redbook; no generics available
31.	Urobak	54	Discontinued per Drugs @FDA; no generics available
32.	Uvadex	58	Deactivated per Redbook; no generics available
33.	Volmax	58	Deactivated per Redbook; no generics available
34.	(b) (4) ***	50	Proposed proprietary name found unacceptable in DMEPA; Product approved under proprietary name (b) (4) RCM # (b) (4).
35.	Ziba-RX	62	discontinued per Drugs @ FDA and RedBook; no generics available
36.	Zobuxa	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases

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

No.	Name	POCA Score (%)
1.	Aldex	50
2.	Amimax	52
3.	Anorex	50
4.	Aurodex	56
5.	Bactex	51
6.	Balmex	52
7.	Bidex	54
8.	Biomox	54
9.	Bisolax	51
10.	Bitex	50
11.	Borofax	61
12.	Bromax	58
13.	Brovex	51
14.	Buffex	50
15.	B-Vex	50
16.	Carbex	50
17.	Casodex	52
18.	Cedax	55
19.	Cefmax	50
20.	Colax	52
21.	Comox	54
22.	Comvax	56
23.	Conex	52
24.	Cophene-X	50
25.	Cotab Ax	64
26.	Dazidox	50
27.	Debrox	52
28.	Dionex	54

No.	Name	POCA Score (%)
29.	Doc-Q-Lax	54
30.	Dothapax	52
31.	Edronax	58
32.	Enzymax	58
33.	Dovonex	60
34.	Estomax	58
35.	Efudex	52
36.	Ez-Ox	56
37.	Fe-Max	53
38.	Fostex	54
39.	Frumax	51
40.	Gen Lax	50
41.	Hyomax	53
42.	Indomax	57
43.	Iodex	52
44.	Iodoflex	50
45.	Irrimax	51
46.	Isotrex	50
47.	J-Max	52
48.	Istodax	58
49.	Koromex	58
50.	Leucomax	53
51.	Librax	53
52.	Lipodox	50
53.	(b) (4) ***	55
54.	Lusonex	54
55.	Monomax Sr	54
56.	Lonox	58
57.	Loprox	52
58.	Lotemax	56

No.	Name	POCA Score (%)
59.	Lotronex	50
60.	Neo-Dex	52
61.	Mentax	51
62.	Monodox	60
63.	Nordox	54
64.	Nasonex	52
65.	Norvaxs	52
66.	Nimbex	50
67.	Nolvadex	50
68.	Novox	57
69.	Phen-Lax	51
70.	Phenolax	52
71.	Pseudo Max	50
72.	Prezcobix	50
73.	Relovox	50
74.	Rommix	50
75.	Renormax	53
76.	Rondex	54
77.	Rozex	60
78.	Rybix***	50
79.	Salvax	50
80.	Senolax	54
81.	Senox	54
82.	(b) (4)***	50
83.	Sina-12X	52
84.	Sonamox	53
85.	Sronyx	50
86.	Stool-Lax	52
87.	Sumox	52
88.	Subutex	50

No.	Name	POCA Score (%)
89.	Symax	52
90.	Sytobex	56
91.	Suprax	52
92.	Theomax	54
93.	Tomudex	50
94.	Topex	55
95.	Ucerax	52
96.	Topamax	54
97.	Urdox	50
98.	Valpax	52
99.	Vanex	52
100.	(b) (4)***	54
101.	Vionex	56
102.	Visonex	51
103.	Vitrax	50
104.	Vortex	54
105.	Xolex	53
106.	Xolox	56
107.	Xopenex	50
108.	X-Wax	50
109.	(b) (4)***	52
110.	Yf-Vax	50
111.	Z-Cof Lax	54
112.	Zinx	50
113.	Zenapax	53
114.	(b) (4)***	54
115.	Zmax	63
116.	(b) (4)***	51
117.	Zonatuss	52
118.	Zostavax	56

No.	Name	POCA Score (%)
119.	Zostrix	51
120.	Zotex Hc	50
121.	Zotex La	50
122.	Zotex Pe	50
123.	Zotex-Gp	50

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/s/

JUSTINE HARRIS
04/01/2016

DANIELLE M HARRIS
04/01/2016