

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205388Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management
Proprietary Name Review**

Date: November 7, 2013

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Drug Names and Strengths: Omidria (Phenylephrine / Ketorolac) solution
61 mM (12.37 mg/mL)/11 mM (4.24 mg/mL)

Application Type/Number: IND 78227 and NDA 205388

Applicant/Sponsor: Omeros

OSE RCM #: 2013-1321 and 2013-2257

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Omidria, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the May 22, 2013 (IND) and September 27, 2013 (NDA) proprietary name submissions.

- Active Ingredient: Phenylephrine HCl and Ketorolac Tromethamine
- Indication of Use: (b) (4) prevention of intraoperative miosis and reduction of early postoperative pain in intraoperative lens replacement surgery.
- Dosage Form: Injection solution concentrate
- Strength: 61 mM (12.37 mg/mL) and 11 mM (4.24 mg/mL)
- Dose and Frequency: 4 mL diluted in 500 mL irrigation solution titrated to effect
- How Supplied: Glass vials, each enclosed in a carton, 10 vials per cardboard box
- Storage: Room temperature, protect from light

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Transplant and Ophthalmic Products (DTOP) concurred with the findings of OPDP's promotional 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 name.¹

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation for the proposed name, Omidria, in their submission. This proprietary name is comprised of a single word that does not contain any components such as a modifier, route of administration, dosage form, etc.

2.2.3 FDA Name Simulation Studies

Sixty-five practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products.

In the outpatient study, 21 out of 23 participants interpreted the name correctly. The only two misinterpretations resulted from erroneously omitting the letter 'i' by two participants.

In the voice study, 13 out of 19 participants identified the name correctly. Common misinterpretations included confusion between the letters 'i' with 'e' or 'y' and consonants such as 'd' with 't' and 'm' with 'v'.

In the inpatient study only 20 out of 23 participants identified the name correctly (Omidria irrigation or Omidira). The errors included misinterpretations of the letter 'a' with 'n', erroneously adding the letter 'r' in the 3rd position, and confusing the letter 'm' with the string 'sv'.

All of the identified misinterpretations were considered in the search and evaluation of phonetically and orthographically similar names (see Appendix B).

Appendix C contains the interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 10, 2013 e-mail, the Division of Transplant and Ophthalmic Products (DTOP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

¹ The October 28, 2013 search of the United States Adopted Name (USAN) stems.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name. These variations were used in the search for names similar to Omidria. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Omidria identified by the primary reviewer, the Expert Panel Discussion (EPD) and (b) (4). Our analysis of the 27 names determined all 27 names will not pose a risk for confusion as described in Appendices D through E.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Midrin	(b) (4)	Anadrol	FDA	Omniderm	FDA
Orudis	(b) (4)	Aniline	FDA	Ondrox	FDA
AeroBid	FDA	Aredia	FDA	Orencia	FDA
Amethia	FDA	Avandia	FDA	Ovidrel	FDA
Amidal	FDA	Ocudox	FDA	Ozurdex	FDA
Amidate	FDA	Omnaris	FDA	Amoclan	FDA
Amidrine	FDA	Omiderm	FDA	Amikacin	FDA
Amitiza	FDA	Omnicef	FDA		FDA
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Mydriacyl	(b) (4)	Adria	FDA		
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Apidra	FDA	Omedia	FDA		

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Transplant and Ophthalmic Products via e-mail on October 25, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Transplant and Ophthalmic Products on October 30, 2013, they stated no additional concerns with the proposed proprietary name, Omidria.

3 CONCLUSIONS

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

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 27, 2013 are altered, the name must be resubmitted for review.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. ***Access Medicine*** (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. ***Red Book*** (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. ***Lexi-Comp*** (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations*** (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy*** (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.²

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

² National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the

⁴ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

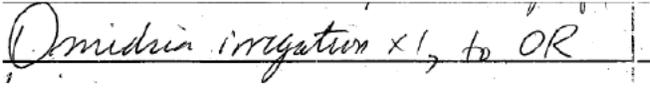
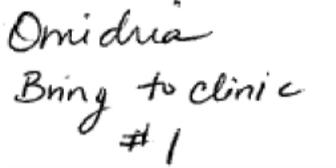
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name,	Scripted May Appear as	Spoken May Be Interpreted as
Upper case O	A, O, U	Any vowel
Lower case o	c, a, u, e	Any vowel
Lower case m	rn, nn, n, v, w, wi, vi, onc, z, sv	Em
Lower case i	e, l, c, a	Any vowel
Lower case d	ci, cl, ol, t, ch	B, t
Lower case r	s, n, e, v	---
Lower case i	e, l, c, a	Any vowel
Lower case a	el, o, u, e, i	Any vowel
Letter Strings	Scripted May Appear as	Scripted Sound as
ri, ia	m, n	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Omidria Study (Conducted on June 27, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> 	Omidria Bring to clinic Dispense #1
<u>Outpatient Prescription:</u> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Omidria

As of Date 6/27/2013

192 People Received Study

65 People Responded

Study Name: Omidria

Total	23	19	23	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
OMDRIA	1	0	0	1
OMEDIREA	0	1	0	1

OMETRIA	0	1	0	1
OMIDRA	1	0	0	1
OMIDRIA	21	13	9	43
OMIDRIA IRRIGATION	0	0	11	11
OMIDRIN IRRIGATION	0	0	1	1
OMITRIA	0	2	0	2
OMRIDRIA	0	0	1	1
OMYDRIA	0	1	0	1
OSVIDRIA IRRIGATION	0	0	1	1
OVITRIA	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Omidria	Failure preventions
1.	Midrin	isometheptene /dichloralphenazone /acetaminophen	Look alike	The pair has sufficient orthographic differences.
2.	Omiderm	Wound dressing polyurethane foam	Look alike	The name was identified in Red Book (as discontinued). USPTO identified the trade name as cancelled. Martindale's identified the product as foreign available in Canada. This wound dressing does not contain a drug and we were unable to find product characteristics in commonly used drug databases.
3.	AeroBid	Flunisolide	Look alike	The pair has sufficient orthographic differences.
4.	Omnaris	Ciclesonide	Look alike	The pair has sufficient

				orthographic differences.
5.	Omnicef	Cefdinir	Look alike	The pair has sufficient orthographic differences.
6.	Orencia	Abatacept	Look alike	The pair has sufficient orthographic differences.
7.	Mydriacyl	Tropicamide	Sound alike	The pair has sufficient phonetic differences.
8.	Adria	Doxorubicin	Sound alike	The search term Adria used in Access Medicine identified the product doxorubicin however it is not an approved US brand name. The pair has sufficient phonetic differences.
9.	Omniderm	Fluocinolone	Look alike	The name was identified in Red Book. Unable to duplicate the search results in Red Book (likely misspelling of Omiderm). Martindale's identified the name as foreign available in Italy. In the US Fluocinolone is marketed under the names Synlar, Retisert, Fluotrex, Fluonid, Flouocet, Dermotic, Derma-smooth/FS, Capex and with the generic name.
10.	---	Aniline	Look alike	The name was identified in Red Book. The product is a chemical reagent used in manufacturing and not a medication.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p>Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	<p>Amidrine (isometheptene /dichloralphenazone /acetaminophen) Capsule</p> <p><u>Strength:</u> 65 mg /100 mg/325 mg</p> <p><u>Dose, Route and</u> <u>Frequency:</u> 2 capsules orally at once, followed by one capsule every hour until pain is relieved, up to 5 capsules within a twelve hour period as needed.</p>	<p>Orthographic similarity Both names have one upstroke in the same positions. When scripted Amidr- may look like Omidr-</p> <p>Overlapping product characteristics Single strength</p>	<p>Orthographic differences The suffix -ia in Omidria appears shorter compared to the suffix -ine in Amidrine</p> <p>Key differences in product characteristics <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 2 capsules or 1 capsule).</p> <p><u>Frequency:</u> Omidria is administered once during surgery compared to Amidrine which is administered every hour for up to 5 hours as needed for pain.</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Orudis (Ketoprofen) Capsule <u>Strength:</u> 25 mg, 50 mg and 75 mg <u>Dose, Route and Frequency:</u> orally 25 mg to 75 mg three times daily or 50 mg four times daily as needed for pain.	Orthographic similarity Both names start with the same letter 'O', and have one upstroke in the same position. When scripted the prefix Omi- may look like Oru-.	Orthographic differences The suffix -dria in Omidria appears elongated compared to the suffix -dis in Orudis Key differences in product characteristics <u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 25 mg, 50 mg and 75 mg] <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 25 mg to 75 mg). <u>Frequency:</u> Omidria is administered once during surgery compared to Orudis which is administered three to four times daily as needed for pain.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
3.	<p>Amethia (levonorgestrel/ ethinyl estadiol and ethinyl estardiol) tablets in a kit</p> <p><u>Strength:</u> 0.15 mg/ 0.03 mg and 0.01 mg</p> <p><u>Dose, Route and</u> <u>Frequency:</u> 1 tablet orally daily</p>	<p>Orthographic similarity</p> <p>Both names have the same number of letters (n=7) and have an upstroke in the same position. When scripted the prefix Omi- may look like Ame-</p> <p>Overlapping product characteristics Single strength</p>	<p>Orthographic differences The suffix -thia in Amethia has an additional upstroke 'h' compared to the suffix -dria in Omidria which gives the names different shape.</p> <p>Key differences in product characteristics</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 1 tablet).</p> <p><u>Frequency:</u> Omidria is administered once during surgery compared to Amethia which is administered daily.</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
4.	<p>Amidal (guaifenesin/ phenylephrine) extended release tablet</p> <p><u>Strength:</u> 300 mg/20 mg</p> <p><u>Dose, Route and</u> <u>Frequency:</u> 1 to 2 tablets orally every 12 hours as needed.</p> <p>Additional info: formulation is off the market</p>	<p>Orthographic similarity</p> <p>Both names have an upstroke in the same position. When scripted the prefix Omi- may look like Ami-.</p> <p>Overlapping product characteristics Single strength</p>	<p>Orthographic differences The suffix -dria in Omidria appears elongated compared to the suffix -dal in Amidal. Also, Amidal has an additional upstroke l giving the names different shape.</p> <p>Key differences in product characteristics</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs.1 to 2 tablets).</p> <p><u>Frequency:</u> Omidria is administered once during surgery compared to Amidal which is administered every 12 hours as needed.</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
5.	Amitiza (Lubiprostone) Capsule <u>Strength:</u> 8 mcg and 24 mcg <u>Dose, Route and Frequency:</u> 8 mcg to 24 mcg orally twice daily	Orthographic similarity Both names have the same number of letters (n=7) and have 1 upstroke in the same position. When scripted the prefix Omi- may look like Ami-.	Key differences in product characteristics <u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 8 mcg and 24 mcg] <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 8 mcg to 24 mcg) . <u>Frequency:</u> Omidria is administered once during surgery compared to Amitiza which is administered twice daily.
6.	Anadrol / Anadrol-50 (Oxymetholone) tablet <u>Strength:</u> 50 mg <u>Dose, Route and Frequency:</u> 1 to 5 mg/kg/day orally (adults and children) range example 25 mg to 250 mg per day	Orthographic similarity Both names have the same number of letters (n=7) and have an upstroke in the same position. When scripted the prefix Omi- may look like Ana-. Overlapping product characteristics Single strength	Orthographic differences Anadrol has an additional upstroke 'l' and Omidria does not giving the names different shape. Key differences in product characteristics <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 25 mg to 250 mg). <u>Frequency:</u> Omidria is administered once during surgery compared to Anadrol which is administered daily.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
7.	<p>Aredia (Pamidronate) injection</p> <p><u>Strength:</u> 30 mg, 60 mg and 90 mg</p> <p><u>Dose, Route and Frequency:</u> 60 mg to 90 mg once intravenously or 30 mg daily on 3 consecutive days or 90 mg every 3 to 4 weeks.</p>	<p>Orthographic similarity Both names have 1 upstroke in the same position.</p> <p>Overlapping product characteristics Frequency (once)</p>	<p>Orthographic differences The suffix -dria in Omidria appears elongated compared to the suffix -dia in Aredia.</p> <p>Key differences in product characteristics</p> <p><u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 30 mg, 60 mg or 90 mg]</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 30 mg to 90 mg).</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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.	Avandia (Rosiglitazone) tablet <u>Strength:</u> 2 mg, 4 mg, and 8 mg <u>Dose, Route and</u> <u>Frequency:</u> 2 mg to 4 mg twice daily or 4 mg to 8 mg daily orally.	Orthographic similarity Both names have the same number of letters (n=7) and have 1 upstroke in similar positions. When scripted the prefix Omi- may look like Ava- Overlapping product characteristics Numerical overlap (4 mg vs. 4 mL/500 mL)	Orthographic differences The suffix -dria in Omidria appears elongated compared to the suffix -dia in Avandia Key differences in product characteristics <u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 2 mg to 8 mg] <u>Frequency:</u> Omidria is administered once during surgery compared to Avandia which is administered once or twice daily.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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.	Ocudox (Doxycycline Hyclate) Capsule <u>Strength:</u> 50 mg <u>Dose, Route and Frequency:</u> 50 mg to 100 mg orally once or twice daily orally. 300 mg once followed by a second dose in one hour once.	Orthographic similarity Both names start with the same letter ‘O’, and have 1 upstroke in the similar positions. When scripted Omid- may look like Ocud- Overlapping product characteristics Single strength, and frequency (once)	Orthographic differences The suffix -ria in Omidria appears elongated compared to the suffix -ox in Ocudox Key differences in product characteristics <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 50 mg, 100 mg or 300 mg).
10.	Ondrox (multivitamin with minerals) extended release tablet <u>Strength:</u> Single strength. <u>Dose, Route and Frequency:</u> 1 tablet orally daily	Orthographic similarity Both names start with the same letter ‘O’, and have 1 upstroke in similar positions. Overlapping product characteristics Single strength	Orthographic differences The prefix Omid- in Omidria appears elongated compared to the prefix Ond- in Ondrox Key differences in product characteristics <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 1 tablet). <u>Frequency:</u> Omidria is administered once during surgery compared to Ondrox which is administered daily.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
11.	<p>Ovidrel (choriogonadotropin alfa) injection</p> <p><u>Strength:</u> 250 mcg/0.5 mL</p> <p><u>Dose, Route and Frequency:</u> 250 mcg subcutaneously one day following the last dose of follicle stimulation agent.</p>	<p>Orthographic similarity Both names start with the same letter ‘O’, have the same number of letters (n=7) and have 1 upstroke in the same position.</p> <p>Overlapping product characteristics Single strength, frequency (once)</p>	<p>Orthographic differences Ovidrel has an additional upstroke ‘l’ at the end and Omidria does not giving the names different shapes. Also the infix -mi- in Omidria appears elongated compared to the infix -vi- in Ovidrel.</p> <p>Key differences in product characteristics</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 250 mcg).</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	<p>Ozurdex (dexamethasone intravitreal implant)</p> <p><u>Strength:</u> 0.7 mg per implant</p> <p><u>Dose, Route and</u> <u>Frequency:</u> one implant injected intravitreally once</p>	<p>Orthographic similarity Both names start with the same letter ‘O’, have the same number of letters (n=7) and have 1 upstroke in similar positions.</p> <p>Overlapping product characteristics Single strength, frequency (once), similar route (intraocular vs. intravitreal)</p>	<p>Orthographic differences The suffix dria- in Omidria appears elongated compared to the suffix -dex in Ozurdex.</p> <p>Key differences in product characteristics</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. 1 implant).</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	Amoclan (Amoxicillin and clavulanate potassium) for oral suspension <u>Strength:</u> 600 mg/42.9 mg per 5 mL <u>Dose, Route and Frequency:</u> 3 mL, 4.5 mL, 6 mL, 7.5 mL, 9 mL, 10.5 mL, 12 mL, and 13.5 mL orally twice daily	Orthographic similarity Both names have the same number of letters (n=7) have 1 upstroke in the same position. When scripted the prefix Omi- may look like Amo- Overlapping product characteristics Single strength	Orthographic differences The suffix -dria in Omidria appears elongated compared to the suffix -clan in Amoclan. Key differences in product characteristics <u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs 3 mL, 4.5 mL, 6 mL, 7.5 mL, 9 mL, 10.5 mL, 12 mL, and 13.5 mL). <u>Frequency:</u> Omidria is administered once during surgery compared to Amoclan which is administered twice daily.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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.	Amikacin injection <u>Strength:</u> 50 mg/mL and 250 mg/mL <u>Dose, Route and Frequency:</u> 7.5 mg/kg every 12 hours (500 mg to 750 mg) or 5 mg/kg (350 mg to 500 mg) every 8 hours or 250 mg twice daily intramuscularly or intravenously. Renal adjustment may reduce the frequency to daily.	Orthographic similarity Both names have 1 upstroke in the same position. When scripted the prefix Ami- may look like Omi-	Orthographic differences The suffix -dria in Omidria appears shorter compared to the suffix -kacin in Amikacin. Key differences in product characteristics <u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 50 mg/mL and 250 mg/mL] <u>Frequency:</u> Omidria is administered once during surgery compared to Amikacin which is administered every 8 hours, 12 hours or daily. <u>Route:</u> Omidria is administered intraocularly compared to Amikaicin which can be administered either intramuscularly or intravenously and therefore the route must be specified on the order. There is no overlap in the route.

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
15.	<p>Omedia (Benzocaine) solution</p> <p><u>Strength:</u> 20 %</p> <p><u>Dose, Route and Frequency:</u> one to several drops into the affected ear as needed for pain</p> <p>Product was only identified in Red Book (as discontinued) and therefore full product characteristics are not available.</p>	<p>Orthographic and Phonetic similarity Both names start with the same letter ‘O’ and have one upstroke in the same position. When scripted the prefix Omi- may look and sound like Ome-</p> <p>Overlapping product characteristics Single strength</p>	<p>Orthographic and phonetic differences The suffix -dria in Omidria appears elongated compared to the suffix -dia in Omedia.</p> <p>Key differences in product characteristics</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. one to several drops).</p> <p><u>Frequency:</u> Omidria is administered once during surgery compared to Omedia which is administered as needed for pain.</p> <p><u>Availability and Prescribing Data:</u> Benzocaine ear solutions are currently unapproved drugs and therefore the time they will be available on the market is limited. If companies decide to file an NDA for a benzocaine ear solution the Sponsor will be required to submit a new proprietary name for review or market the product using the established name. Preliminary drug use data did not show any prescribing of the product Omedia.</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	<p>Amidate (Etomidate), injection</p> <p><u>Strength:</u> 20 mg/10 mL vial / ampoule and 40 mg/20 mL syringe/vial/ ampoule</p> <p><u>Dose, Route and Frequency:</u> Adults and children over 10 years of age, 0.2 mg/kg to 0.6 mg / kg intravenously over 30 to 60 seconds to induce anesthesia</p>	<p>Orthographic similarity Both names have the same number of letters (n=7) and have 1 upstroke in the same position. When scripted Amid- may look like Omid-</p> <p>Overlapping product characteristics Frequency (once).</p>	<p>Orthographic and phonetic differences Amidate has an additional upstroke ‘t’ in the 6th position and Omidria does not giving the names different shape and appearance.</p> <p>Key differences in product characteristics</p> <p><u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 20 mg/10 mL and 40 mg /20 mL]</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. weight based dose ranging from 6 mg to 60 mg (30 kg to 100 kg).</p>

No.	Proposed name: Omidria Dosage Form(s): injection solution Strength: 61 mM (12.37 mg/mL) Phenylephrine and 11 mM (4.24 mg/mL) Ketorolac Usual Dose: 4 mL in 500 mL intraocular irrigation solution titrated to effect.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
17.	<p>Apidra (Insulin glulisine), injection</p> <p><u>Strength:</u> 300 units/3 mL prefilled pen and 1000 units/10 mL vial</p> <p><u>Dose, Route and Frequency</u> 0.5 to 1 unit/ kg /day divided based on glucose levels and individualized, administered subcutaneously as an injection, as a continues subcutaneous infusion (pump) or intravenously.</p> <p>40 kg to 100 kg equal approximately 20 to 100 units per day divided 3 times (meals)</p>	<p>Orthographic similarity Both names have 1 upstroke in the same position. When scripted the suffix dria- may look like dra-</p> <p>POCA phonetic and orthographic combined score is 62%.</p>	<p>Orthographic and phonetic differences Apidra has a down stroke in the 2nd position and Omidria does not, giving the names different shape. Also the infix -mi- in Omidria appears elongated compared to the infix -pi- in Apidra.</p> <p>Key differences in product characteristics</p> <p><u>Strength</u> There is no overlap in strength [61 mM (12.37 mg/mL) /11 mM (4.24 mg/mL) vs. 300 units/3 mL 1000 units/10 mL]</p> <p><u>Dose:</u> There is no overlap in dose (4 mL/500 mL irrigation titrated to effect vs. approximately 7 units to 33 units per dose).</p>

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/s/

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