

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22404Orig1s000

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**

Date: January 27, 2010

To: Renata Albrecht, MD, Director
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Division of Medication Error Prevention and Analysis (DMEPA)

From: Tselaine Jones Smith, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Oravig (Miconazole) Tablets, 50 mg

Application Type/Number: NDA 022404

Applicant: BioAlliance Pharma

OSE RCM #: 2009-2209

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

CONTENTS

1	INTRODUCTION.....	3
2	METHODS.....	3
2.1	Database and Information Sources	3
3	RESULTS.....	3
4	CONCLUSIONS AND RECOMMENDATIONS.....	3
5	REFERENCES	4

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Oravig, acceptable in OSE Review #2009-1462, dated November 10, 2009. The Division of Special Pathogen and Transplant Products did not have any concerns with the proposed name, Oravig, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on August 27, 2009.

2 METHODS

2.1 DATABASE AND INFORMATION SOURCES

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 5) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2009-1462. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates.

3 RESULTS

The searches of the databases yielded one (n=1) name, (b) (4) which was thought to look similar to Oravig and represent a potential source of drug name confusion.

The name, (b) (4) was evaluated using Failure Mode and Effects Analysis (FMEA). The findings of the FMEA indicate that the proposed name, Oravig, is not likely to result in name confusion with (b) (4) for the reasons presented in Appendix A.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Oravig, as of January 15, 2010.

4 CONCLUSIONS AND RECOMMENDATIONS

The proprietary name risk assessment findings indicate that the proposed name, Oravig, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Oravig, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Special Pathogen and Transplant Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

5 REFERENCES

1. OSE review # 2009-1462 dated November 10, 2009; Proprietary Name Review of Oravig; Tselaine Jones Smith, Safety Evaluator.

2. *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.

3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

4. *CDER Proposed Names List*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

Appendix A: Single strength product with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days	
(b) (4)				

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22404	ORIG-1	BIOALLIANCE PHARMA	Lauriad (miconazole (b) (4) tablet)

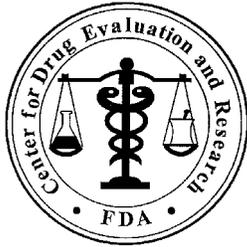
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**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: November 10, 2009

To: Renata Albrecht, MD, Director
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Through: Kristina C. Arnwine, PharmD, Team Leader
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Division of Medication Error Prevention and Analysis (DMEPA)

From: Tselaine Jones Smith, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Oravig (Miconazole) Tablets, 50 mg

Application Type/Number: NDA # 22-404

Applicant/Applicant: BioAlliance Pharma

OSE RCM #: 2009-1462

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CONTENTS

EXECUTIVE SUMMARY	3
1 BACKGROUND	3
1.1 Introduction	3
1.2 Product Information	3
2 METHODS AND MATERIALS	3
2.1 Search Criteria	3
2.2 FDA Prescription Analysis Studies	4
2.3 External Proprietary Name Risk Assessment	4
3 RESULTS	5
3.1 Database and Information Sources	5
3.2 Expert Panel Discussion	5
3.3 FDA Prescription Analysis Studies	5
3.4 External Study Assessment	5
3.5 Comments from the Division of Special Pathogens and Transplant Products	5
3.6 Safety Evaluator Risk Assessment	6
4 DISCUSSION	6
5 CONCLUSIONS AND RECOMMENDATIONS	6
5.1 Comments To The Applicant	6
6 REFERENCES	7
APPENDICES	9

EXECUTIVE SUMMARY

Oravig is the proposed proprietary name for miconazole tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Additionally, our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Oravig, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from BioAlliance Pharma for an assessment of the proposed proprietary name, Oravig, for its promotional nature and the potential to contribute to medication errors. BioAlliance Pharma contracted with [REDACTED] ^{(b) (4)} to conduct an external name study and the results of this evaluation have also been submitted for review and comment.

1.2 PRODUCT INFORMATION

Oravig (miconazole) is indicated for the treatment of oropharyngeal candidiasis. The recommended dose is one 50 mg tablet to the upper gum region (canine fossa) once daily for 14 consecutive days. Oravig should be applied in the morning, after brushing the teeth. The tablet should be placed against the upper gum just above the incisor tooth (canine fossa) and held in place with slight pressure over the facial skin where the tablet was placed for 30 seconds to ensure adhesion. Once applied, Oravig is designed to stay in position until it dissolves. Oravig should be applied to alternate sides of the mouth with each application. Oravig will be packaged in bottles of 14 tablets. The product is stored at room temperature.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Oravig.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘O’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

² Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

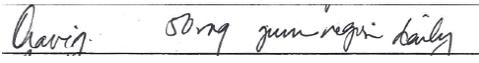
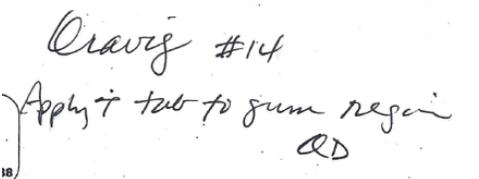
To identify drug names that may look similar to Oravig, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (one, capital letter ‘O’) and downstrokes (one, lower case letter ‘g’). Additionally, several letters in Oravig may be vulnerable to ambiguity when scripted, including the capital letter ‘O’ may appear as capital letters ‘A’, ‘Ci’, ‘D’, ‘E’, ‘I’ or ‘S’; lower case letter ‘r’ may appear as lower case letters ‘n’, ‘s’, ‘t’ or ‘v’; lower case ‘a’ may look like lower case letters ‘o’, ‘u’ or ‘e’; lower case letter ‘v’ may appear as lower case letters ‘n’, ‘s’, ‘u’ or ‘r’; Lower case ‘i’ may appear as lowercase ‘r’, ‘s’, ‘l’ or ‘e’; and, lower case letter ‘g’ may appear as lower case letters ‘p’, ‘j’, ‘y’ or ‘z’. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Oravig.

When searching to identify potential names that may sound similar to Oravig, the DMEPA staff search for names with similar number of syllables (three), stresses (OR-a-vig, or-A-vig or or-a-VIG), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as ‘-vig’ may sound similar to ‘-big’. The Applicant’s intended pronunciation of the proprietary name was provided as OR-a-vig.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Oravig Study (conducted on August 27, 2009)

HANDWRITTEN PRESCRIPTION ORDERS	VERBAL PRESCRIPTION ORDER
<p><u>Inpatient Prescription Order:</u></p> 	<p>Oravig 50 mg Apply one tab to gum daily</p>
<p><u>Outpatient Prescription Order:</u></p> 	

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA’s database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator’s Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 24 names as having some similarity to the name Oravig.

Eighteen of the names were thought to look like Oravig. These include Avage, Unasyn, Coreg, Orabase, Oracit, Oraverse, Amvaz, (b) (4) Acanya, Conray, Eraxis, Orudis, (b) (4) (b) (4) Orap, (b) (4) Actiq and Amrix. Five of the names were thought to look and sound like Oravig. These include (b) (4) (b) (4) Oraxyl, Orafix and Oraqix. The final name, Lorabid, was thought to sound like Oravig.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 20, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Oravig.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of eighteen practitioners responded but none of the responses overlapped with any existing or proposed drug names. Thirteen (n=13) of the participants interpreted the name correctly as 'Oravig'. Correct interpretation occurred in both the inpatient (n=6) and the outpatient (n=4) written studies. In the verbal studies, three (n=3) of the participants interpreted the name correctly as 'Oravig'. The remaining responses were misspelled variations of the proposed name. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY ASSESSMENT

The Applicant's external name study conducted by (b) (4) identified a total of 20 names.

Seven of the names were identified as having similar orthographic appearance to Oravig. These include Orudis, Orap, Coreg, DDAVP, Oracea, Orenzia and Oseltamivir. Seven names were identified as having a similar sound to Oravig. These include Orabase, Oraquick, Lorabid, Oracit, Oramorph SR, Oranyl and Orazinc. The final six names were thought to look and sound similar to Oravig. These include Oruvail, Orajel, Zomig, Nuvaring, Orapred and Ovral.

(b) (4) identified five names (Orudis, Orap, Coreg, Lorabid, and Oracit) which were also identified by DMEPA staff and in the Expert Panel Discussion. The remaining 15 names will be added to Section 3.6 for further analysis. (b) (4) concluded the name did not pose a risk for name confusion with the identified products.

3.5 COMMENTS FROM THE DIVISION OF SPECIAL PATHOGENS AND TRANSPLANT PRODUCTS

In response to the OSE email on September 16, 2009, DDOP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

DMEPA notified the Division via e-mail that we had no objections to the proposed proprietary name; Oravig, on October 20, 2009. Per e-mail correspondence from the Division on October 27, 2009, they indicated they concur with our assessment of the proposed proprietary name, Oravig.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified an additional nine names (Diamox, Unicap, Anacin, Aricept, Comvax, Amerge, Arava, (b) (4) and (b) (4)) which were thought to look similar to Oravig represent a potential source of drug name confusion.

4 DISCUSSION

Neither DDMAC nor the review Division had concerns with the proposed name. DMEPA did not identify any issues that would render the name objectionable other than names that were potential sources of confusion because of their similar sound and/or appearance to Oravig.

As such, a total of 48 names were identified as potential sources of drug name confusion with Oravig.

Our evaluation noted the name, (b) (4), was identified to have look-alike similarities to Oravig. We determined this name was misspelled during the search process (i.e. (b) (4) for Arava which was identified by the primary safety evaluator) thus (b) (4) was eliminated from further evaluation. Twelve (n=12) names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with the remaining 35 names and lead to medication errors. This analysis determined that the name similarity between Oravig was unlikely to result in medication errors with any of the 35 products for the reasons presented in Appendices D through K. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Oravig, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Oravig, for this product at this time.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name will be re-reviewed.

For questions or clarifications, please contact Nitin Patel, OSE Project Manager, at 301-796-5412.

5.1 COMMENTS TO THE APPLICANT

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

Oravig will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

6 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.

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

DARRTS is a government database used to track individual submissions and assignments in 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. *Electronic online version of the FDA Orange Book* (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. *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.

10. 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.

11. 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.

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

15. Lexi-Comp (www.lexi.com)

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

16. Medical Abbreviations Book

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

17. SDI, Physician Drug and Diagnosis Audit (PDDA) with Pain Panel. Jan04 - Sep09. Extracted Oct 09.

SDI's Physician Drug & Diagnosis Audit (PDDA) with Pain Panel is a monthly survey designed to provide descriptive information on the patterns and treatment of diseases encountered in office-based physician practices in the U.S. The survey consists of data collected from over 3,200 office-based physicians representing 30 specialties across the United States that report on all patient activity during one typical workday per month. These data may include profiles and trends of diagnoses, patients, drug products mentioned during the office visit and treatment patterns. The Pain Panel supplement surveys over 115 pain specialists physicians each month. With the inclusion of visits to pain specialists, this will allow additional insight into the pain market. The data are then projected nationally by physician specialty and region to reflect national prescribing patterns.

SDI uses the term "drug occurrences" to refer to the number of times a product has been reported on a patient information form during an office-based patient visit for that period. It is important to note that a "drug occurrence" does not necessarily result in a prescription being generated. A "drug occurrence" can result from a prescription written, a sample given, a recommendation for OTC products, recommendation with sample, a product dispensed or administered in the office, a hospital order, a nursing home order or a combination of these.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment 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 focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the 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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.⁵ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products

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

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

⁵ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
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 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, the DMEPA staff also 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 staff conducts searches of 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 using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of 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 Analysis 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 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.⁶ 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 use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. 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?”

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. 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

⁶ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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.

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 Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC'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.

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 is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Applicant 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. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug 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 a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but

at great financial cost to the Applicant 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 Applicants’ 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. (See Section 4 for limitations of the process).

Appendix B: FDA Prescription Study Responses.

Inpatient Prescription	Outpatient Prescription	Voice Prescription
Oravin	Oraviz	Oravick
Oravig	Oravig	Oravig
Oravig	Oravig	Oravig
Oravij	Oravig	Oravig
Oravig	Oravig	
Oravig		
Oravig		
Oravij		
Oravig		

Appendix C: Names Lacking Orthographic and/or Phonetic Similarity

Name	Similarity to Oravig
Orabase	Look
Orap	Look
Oseltamivir	Look
Orabuse	Sound
Oramorph SR	Sound
Orajel	Look and Sound
Zomig	Look and Sound
Nuvaring	Look and Sound
(b) (4)	Look
Orapred	Look and Sound
Ovral	Look and Sound
Aricept	Look

Appendix D: Drug products that are discontinued and no generic equivalent is available

Proprietary Name	Similarity to Oravig	Status and Date
Amvaz (amlodipine maleate)	Look	NDA # 21-435 Withdrawn April 16, 2004 Source: DAARTS
Lorabid (loracarbef) for oral suspension, capsules	Sound	NDA # 50-667 and 50-668 Withdrawn by the commissioner on June 18, 2009 Source: DARRTS

Appendix E: Drug names not found in commonly referenced databases (See Section 6, References 1 through 16)

Name	Similarity to Oravig
Oranyl (pseudoephedrine) tablets 60 mg	Look (name identified by (b) (4))

Appendix F: Proprietary names not approved by the Agency

Proprietary Name	Similarity to Oravig	Status
(b) (4) (fentanyl citrate)	Look and Sound	<ul style="list-style-type: none"> The proposed name (b) (4) was an alternate name for NDA #21-947 and was not reviewed by DMEPA NDA #21-947 was approved as Fentora on September 25, 2006
(b) (4) (urofollitropin)	Look	<ul style="list-style-type: none"> Name found unacceptable in OSE Review #00-0326 for NDA #21-289 NDA #21-289 approved as Bravelle on May 6, 2002
(b) (4)		
Ovarex*** (oregovomab)	Look and Sound	<ul style="list-style-type: none"> (b) (4) withdrawn by Sponsor

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

Appendix G: Product that is a diagnostic test

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days
Oraquick Human immunodeficiency virus (HIV) antibody test that usually detects HIV1 and HIV 2.	Sound	N/A	<p>An order for Oraquick would not include the supplemental information such as the frequency, route of administration or duration of use that is required for an Oravig order. However, the instructions for using Oraquick would unlikely be included in an order because the nurse or laboratory technician would know how to use this product.</p> <p>Additionally, since different prescribers and/or institutions may use different HIV tests, it is likely that an order would say 'HIV test' in lieu of the specific brand. Finally, most hospitals will use a blood HIV test in lieu of this screening type of test.</p>

Appendix H: Products with no numerical overlap in dose or strength

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days
Unasyn (Ampicillin sodium/Sulbactam sodium) powder for injection	Look	1.5 grams, 3 grams, 15 grams (pharmacy bulk pack)	1.5 grams to 3 grams every six hours via slow intravenous injection over at least 10 minutes to 15 minutes, or via intravenous infusion over 15 minutes to 30 minutes, or via deep intramuscular injection
Orafix Denture adhesive product line	Sound	0.2%, 2.5%, 52%	Apply to either wet or dry dentures in short strips.

Appendix I: Products with overlap in dose, strength or achievable dose a with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days	
(b) (4)				Strength (50 mg vs. 4 mg or 8 mg) While both products can be taken as a one time dose, Oravig is taken as a one time dose once a day. In addition, Oravig is given over 14 consecutive days and orders for Oravig may include the number of tablets to be dispensed.
Eraxis anidulafungin, injection	Look	50 mg 100 mg	Single 100 mg or 200 mg loading dose given intravenously on Day 1 followed by 50 mg or 100 mg intravenously daily for 7 to 14 days	Dosage Form (tablet vs. injection) Route of administration (oral vs. intravenous)
Avage (tazarotene) cream	Look	0.1%	Apply a pea-sized amount once daily before bedtime to lightly cover the entire face	Dose (50 mg or one tablet vs. pea-sized amount) Dosage Form (tablet vs. cream) Route of administration (oral vs. topical)
Oracit (citric acid and sodium citrate) oral solution	Look	640 mg-490 mg per 5 mL	10 mL (2 teaspoonfuls) to 30 mL (2 tablespoonfuls) orally four times daily given after meals and at bedtime	Dose (50 mg or one tablet vs. 10 mL to 30 mL) Dosage Form (tablet vs. oral solution)
OraVerse (phentolamine mesylate) injection	Look	0.4 mg per 1.7 mL	0.2 mg to 0.8 mg dependent on the amount of local anesthetic administered and following the dental procedure using the same location(s) and techniques (infiltration or block injection) employed for the administration of the local anesthetic	Dosage Form (tablet vs. injection) Frequency of administration (once daily vs. four time daily) Context of use (outpatient, administered by patient vs. administered by a dentist following dental procedures)

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days	
Acanya (benzoyl peroxide and clindamycin phosphate) gel	Look	1.2%/2.5 %	Apply a pea-sized amount to the face once daily	Dose (50 mg or one tablet vs. pea size amount) Dosage Form (tablet vs. gel) Route of administration (oral vs. topical)
Conray (iothalamate meglumine) injection	Look	60%	30 mL to 60 mL via intravenous injection over 30 to 90 seconds dependent on the type procedure	Dosage Form (tablet vs. injection) Route of administration (buccal vs. intravenous) Frequency of administration (once daily vs. one time per procedure)
Oraqix (lidocaine and prilocaine periodontal gel)	Look and Sound	2.5% /2.5%	Apply on the gingival margin (i.e. periodontal pockets) around the selected teeth using the blunt tipped applicator included on the package. Wait 30 seconds before starting treatment. If the anesthesia starts to wear off, re-apply as needed. Maximum dose per treatment session is five cartridges.	Dose (50 mg or one tablet vs. sufficient amount) Dosage Form (tablet vs. gel) Route of administration (oral vs. periodontal pockets) Frequency of administration (once daily vs. as needed per procedure)
Anacin aspirin and caffeine tablets	Look	400 mg/32 mg	Take 2 tablets every 6 hours, while symptoms persist	Frequency of administration (once daily vs. every 6 hours) Although Anacin can be prescribed as 'one tablet', once a day aspirin is usually prophylaxis with either the 81 mg or 325 mg strengths, and does not contain caffeine. This additional information would help differentiate these two products.
Comvax Haemophilus B conjugate and Hepatitis B vaccine, suspension for injection	Look	5 mg/0.5 mL	0.5 mL intramuscular injection at 2,4 and 12 -15 months of age	Dosage Form (tablet vs. suspension for injection) Frequency of administration (once daily vs. one time at 2, 4 and 12-15 months of age) Route of administration (oral vs. intramuscular) Patient population (oral thrush in adults vs. vaccination for infants)

Product name with potential for confusion	Similarity to Oravig	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics
Oravig (miconazole) tablet		50 mg	Apply one (1) tablet to the gum region once daily for 14 days	
Orencia (abatacept) for injection	Look	250 mg	<p><i>Adults > 100 kg:</i> 1000 mg intravenous infusion over 30 minutes every 2 weeks x 2 (i.e., a dose at weeks 0, 2, and 4), then 1000 mg IV over 30 minutes every 4 weeks starting at week 8</p> <p><i>Adults 60–100 kg:</i> 750 mg intravenous infusion over 30 minutes every 2 weeks x 2 (i.e., a dose at weeks 0, 2, and 4), then 750 mg IV over 30 minutes every 4 weeks starting at week 8.</p> <p><i>Adults < 60 kg:</i> 500 mg intravenous infusion over 30 minutes every 2 weeks x 2 (i.e., a dose at weeks 0, 2, and 4), then 500 mg IV over 30 minutes every 4 weeks starting at week 8.</p>	<p>Dosage Form (tablet vs. injection)</p> <p>Route of administration (oral vs. intravenous)</p> <p>Frequency of administration (once daily vs. once every 2 weeks, then once every four weeks)</p>

Appendix J: Potential confusing name with numerical similarity in strength or dose

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Orudis ketoprofen capsules, 25 mg, 50 mg, 75 mg 25 mg to 50 mg (one capsule) orally four times daily 75 mg (one capsule) orally three times daily</p>	<p><i>Orthographic similarities</i> ‘Ora-’ looks similar to ‘Oru-’ when scripted <i>Product characteristic similarities</i> Overlapping strength/dose (50 mg) Similar dosage forms (tablets/capsules)</p>	<p>Orthographic characteristic differences minimize the likelihood of medication error in the usual practice setting. The downstroke of the letter ‘g’ at the end of Oravig and the upstroke of the letter ‘d’ in the middle of the name Orudis differentiate the two names when scripted. In addition to the orthographic differences, although both products have overlapping strengths at 50 mg the frequency for Orudis 50 mg is generally 4 times a day. In contrast the Oravig 50 mg is given once a day.</p>
<p>Amrix cyclobenzaprine hydrochloride extended release capsules, 15 mg and 30 mg 15 mg (one capsule) to 30 mg (one to two capsules) orally once a day</p>	<p><i>Orthographic similarities</i> ‘Oravi-’ looks similar to ‘Amri-’ when scripted <i>Product characteristic similarities</i> Overlapping dose (one tablet/capsule) Similar dosage forms (tablet/ capsule) Overlapping frequency of administration (once a day)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting. The downstroke of the letter ‘g’ at the end of Oravig and the cross stroke of the letter ‘x’ at the end of Amrix differentiate the two names when scripted. Oravig is a single strength product whose strength may be omitted from orders. Amrix is available in multiple strengths and the strength will have to be included on orders. In addition, Amrix strengths do not overlap with the Oravig strength.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Oracea doxycycline extended release capsules, 40 mg</p> <p>One capsule orally in the morning on an empty stomach preferably at 1 hour prior to or 2 hours after meals</p>	<p><i>Orthographic similarities</i> ‘Oravi-’ looks similar to ‘Orace-’ when scripted</p> <p><i>Product characteristic similarities</i> Both products are available as single strengths (50 mg vs. 40 mg) therefore the strength may be omitted from orders</p> <p>Overlapping dose (one tablet/capsule)</p> <p>Similar dosage forms (tablet/capsule)</p> <p>Overlapping frequency of administration (once a day)</p> <p>Overlapping route of administration (oral)</p>	<p>Orthographic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The downstroke of the letter ‘g’ at the end of Oravig and the letter ‘a’ at the end of Oracea differentiate the two names when scripted.</p>
<p>Amerge (naratriptan hydrochloride) tablets, 2.5 mg and 1 mg</p> <p>One tablet as a single dose. If the headache returns or if there is a partial response, the dose may be repeated once after four hours for a maximum of 5 mg in a 24 hour period</p>	<p><i>Orthographic similarities</i> ‘Oravig’ can look similar to ‘Amerge-’ when scripted</p> <p><i>Product characteristic similarities</i> Overlapping dose (one tablet)</p> <p>Overlapping or similar dosage forms (tablet)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The letter ‘e’ at the end of the name allows Amerge to look longer than Oravig when scripted.</p> <p>Oravig is a single strength product whose strength may be omitted from orders. Whereas, Amerge is available in multiple strengths (2.5 mg and 1 mg) and the strength will have to be included on orders. Neither of the Amerge strengths overlap with Oravig.</p> <p>The frequency of administration (once daily vs. single dose, may repeat once after 4 hours) differ between the two products.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Diamox acetazolamide <i>tablets, 125 mg and 250 mg</i> One tablet (250 mg) or two tablets (125 mg) orally every 4 hours <i>injection, 500 mg</i> 250 mg to 375 mg intravenously once daily <i>extended release capsules, 500 mg (Diamox sequels)</i> One capsules (500 mg) orally twice daily</p>	<p><i>Orthographic similarities</i> 'Oravi-' can look like 'Diam-' when scripted</p> <p><i>Product characteristic similarities</i> <i>vs. Diamox tablets</i></p> <p>Overlapping dose (one tablet)</p> <p>Overlapping dosage forms (tablet)</p> <p>Overlapping route of administration (oral) <i>vs. Diamox extended release capsule</i></p> <p>Single strengths products. The strength may be omitted from orders</p> <p>Numerical Similarity (50 mg or 500 mg)</p> <p>Overlapping dosage forms (tablet/capsule)</p> <p>Overlapping route of administration (oral)</p> <p>Potential for achievable dose (250 mg) <i>vs. Diamox injection</i></p> <p>Single strength products. Strength of Oravig will most likely be omitted. Strength of Diamox will most likely be omitted because it's an injectable.</p> <p>Overlapping frequency of administration (once daily)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The downstroke of the letter 'g' at the end of Oravig and the letters '-ox' at the end of Diamox differentiate the two names when scripted. <i>vs. Diamox tablets</i></p> <p>Diamox tablets are available in two strengths (125 mg and 250 mg). Therefore, the strength would have to be specified on orders.</p> <p>Additionally, the difference in the frequency of administration between Oravig (once a day) and Diamox tablets (every 4 hours) helps differentiate the products. <i>vs. Diamox extended release capsules (Diamox sequels)</i></p> <p>Although, there is the potential for numeric similarity in doses (50 mg vs. 500 mg) The numeric similarity would be exacerbated by the addition of a terminal zero to the Oravig dose (e.g., 50.0 mg); however, usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error.</p> <p>However, if an order for Diamox 500 mg BID is misinterpreted as Oravig 500 mg BID the practitioner would have to misinterpret the proprietary name, not recognize that it is an Oravig overdose, and not recognize the incorrect frequency. Additionally, if it is an outpatient order since Oravig comes in a unit-of-use bottle containing 14 tablets; the available bottle would not supply a total single daily dose. <i>vs. Diamox injection</i></p> <p>The dose (50 mg or one tablet vs. 250 mg to 375 mg) differs between the two products.</p> <p>The dosage forms (tablet vs. injection) differ between the two products.</p> <p>The route of administration (oral vs. intravenous) differs between the two products.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Arava leflunamide tablets, 10 mg, 20 mg and 100 mg 20 mg orally once a day</p>	<p><i>Orthographic similarities</i> ‘Oravi-’ can look like ‘Arava’ when scripted</p> <p><i>Product characteristic similarities</i> Potential for overlapping dose (one tablet) Similar dosage forms (tablet)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The downstroke of the letter ‘g’ at the end of Oravig differentiates the two names when scripted.</p> <p>Oravig is a single strength product whose strength may be omitted from orders. Whereas, Arava is available in multiple strengths (10 mg, 20 mg and 100 mg) and the strength will most likely be included on orders.</p> <p>Arava may be initiated at a dose of 100 mg per day for 3 days. However, the 100 mg tablets can only be obtained from the manufacturer.</p> <p>Although an order for Oravig 50 mg daily could be misinterpreted as Arava 50 mg daily the fact that this would be an Arava overdose and the orthographic differences may help minimize this confusion.</p>
<p>Orazinc* <i>zinc gluconate tablets,</i> <i>110 mg</i> Two tablets orally three times daily <i>zinc sulfate capsules, 220 mg</i> One capsule orally three times *This product has two different dosage forms with different active ingredients and different strengths.</p>	<p><i>Orthographic similarities</i> ‘Oravi-’ can look like ‘Orazi-’ when scripted</p> <p><i>Product characteristic similarities</i> Overlapping dose (one) with the capsules Similar dosage forms (tablet/capsule)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The downstroke of the letter ‘g’ at the end of Oravig differentiates it from the downstroke of the letter ‘z’ in the middle and the ending letters ‘-nc’ of Orazinc when scripted.</p> <p>Oravig is a single strength product whose strength may be omitted from orders. Whereas, Orazinc is available in multiple strengths (110 mg and 220 mg) and the strength will have to be included on orders. Neither of these strengths overlap with Oravig.</p> <p>The frequency of administration (once daily vs. three times a day) differs between the two products.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Unicap Multivitamin capsules, chewable tablets, coated tablets One tablet/capsules orally once daily</p>	<p><i>Orthographic similarities</i> ‘Ora’ can look like ‘Uni’ when scripted</p> <p><i>Product characteristic similarities</i> Both Oravig and Unicap are available as single strengths since Unicap, is composed of many vitamins, the strength of each component is generally not listed on an order. Therefore, the strength may be omitted from orders</p> <p>Overlapping dose (one tablet/capsule)</p> <p>Similar dosage forms (tablet/capsule)</p> <p>Overlapping frequency of administration (once daily)</p>	<p>Orthographic and product differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The endings of the two names ‘cap’ vs ‘vig’ look different when scripted which helps to differentiate the products.</p> <p>If strength is present, for Oravig that would prevent misinterpretation of an Oravig prescription for a Unicap prescription.</p> <p>Oravig requires additional instructions for use that may include distinguishers such as ‘apply to the upper gum above the incisor after brushing’; ‘when applying, the tablet should be held in place for 30 seconds with a slight pressure of the finger...’; ‘the tablet will slowly dissolve over time and should be left in place...’</p> <p>Additionally, this product was not found in the 2009 Redbook which indicates it may not be marketed.</p>
<p>Oruvail ketoprofen, extended release capsule 100 mg, 150 mg and 200 mg One capsule once a day</p>	<p><i>Orthographic and phonetic similarities</i> ‘Oravi-’ can look like ‘Oruvai-’ when scripted ‘O-ra-vi-’ can sound like ‘O-ru-vai-’ when spoken</p> <p><i>Product characteristic similarities</i> Overlapping dose (one tablet/capsule)</p> <p>Similar dosage forms (tablet/capsule)</p> <p>Overlapping frequency of administration (once daily)</p>	<p>Orthographic, phonetic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The downstroke of the letter ‘g’ at the end of Oravig differentiates it from the name Oruvail when scripted. In addition, Oruvail contains an upstroke (letter ‘l’) at the end of its name and is longer than Oravig when scripted.</p> <p>The hard ‘g’ sound at the end of Oravig differentiates it from the ‘l’ sound at the end of Oruvail.</p> <p>Oravig is a single strength product whose strength may be omitted from orders. Whereas, Oruvail is available in multiple strengths (100 mg, 150 mg and 200 mg) and the strength will have to be included on orders. Neither strength overlaps with the Oravig strength.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>DDAVP (desmopressin acetate) <i>nasal solution, 0.01%</i></p> <p>One to four sprays intranasally in one to three divided doses</p> <p><i>injection, 4 mcg/mL</i></p> <p>0.2 mcg (0.5 mL) to 0.4 mcg (1 mL) given intravenously or subcutaneously once daily</p> <p><i>tablets, 0.1 mg and 0.2 mg</i></p> <p>0.1 mg to 1.2 mg orally per day given in two to three divided dose</p>	<p><i>Orthographic similarities</i></p> <p>Both names share the letters '-av-' in the third and fourth positions</p> <p><i>Product characteristic similarities</i></p> <p><i>vs. DDAVP nasal solution</i></p> <p>Both products are available as single strengths (50 mg vs. 0.01%) therefore the strength will be omitted from orders</p> <p>Numeric similarity in dose (one)</p> <p>Potential for overlapping frequency of administration (once a day)</p> <p><i>vs. DDAVP injection</i></p> <p>The strength will be omitted from orders (single strength product vs. injection)</p> <p>Overlapping frequency of administration (once daily)</p> <p><i>vs. DDAVP tablets</i></p> <p>Potential for overlapping dose (one tablet)</p> <p>Similar dosage forms (tablets)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>DDAVP looks longer than Oravig when written with all capital letters</p> <p><i>vs. DDAVP nasal solution</i></p> <p>The dosage forms (tablets vs. nasal solution) differ between the two products.</p> <p>The routes of administration (buccal vs. intranasal) differ between the two products.</p> <p><i>vs. DDAVP injection</i></p> <p>The doses (one tablet or 50 mg vs. 0.2 mcg to 0.4 mcg) differ between the two products</p> <p>The dosage forms (tablets vs. injection) differ between the two products</p> <p>The routes of administration (buccal vs. intravenous or subcutaneous) differ between the two products</p> <p><i>vs. DDAVP tablets</i></p> <p>Oravig is a single strength product. Therefore, the strength may be omitted from orders. Whereas DDAVP tablets are available is in two strengths (0.1 mg and 0.2 mg). Thus, the desired strength will be specified on orders. Neither strength overlaps with the Oravig strength.</p> <p>The frequencies of administration (once daily vs. two to three times a day) differ between the two products</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
<p>Oraxyl (doxycycline hyclate) capsule 20 mg One capsule orally twice daily</p>	<p><i>Orthographic similarities</i> ‘Oravig’ can look similar to ‘Oraxy-’ when scripted</p> <p><i>Product characteristic similarities</i> Both Oravig and Oraxyl are available as single strengths (50 mg vs. 20 mg) therefore the strength may be omitted from orders</p> <p>Overlapping dose (one) Similar dosage forms (tablet/capsule)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The upstroke of the letter ‘l’ at the end of Oraxyl differentiates it from the name Oravig when scripted.</p> <p>The frequency of administration (once daily vs. twice daily) differs between the two products.</p> <p>Oravig requires additional instructions for use that may include distinguishers such as ‘apply to the upper gum above the incisor after brushing’; ‘when applying, the tablet should be held in place for 30 seconds with a slight pressure of the finger...’; ‘the tablet will slowly dissolve over time and should be left in place...’</p>
<p>Coreg (carvedilol) tablets 3.125 mg, 6.25 mg, 12.5 mg and 25 mg 6.25 mg to 50 mg orally twice daily</p>	<p><i>Orthographic similarities</i> The letters ‘Ora-’ look similar to ‘-ore-’ when scripted</p> <p>Both names end with a downstroke (letter ‘g’)</p> <p><i>Product characteristic similarities</i> Potential for overlapping dose (50 mg)</p> <p>Similar dosage forms (tablets)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The letter ‘C’ at the beginning of Coreg helps to differentiate it from Oravig when scripted</p> <p>The six letters of Oravig allows it to look longer than the five letters of Coreg when scripted</p> <p>The strengths (50 mg vs. 3.125 mg, 6.25 mg, 12.5 mg or 25 mg) differ between the two products.</p> <p>Even though there is the potential for overlapping doses (50 mg), individual Coreg doses higher than 25 mg are not generally used.</p> <p>Based upon office-based physician survey data from SDI, Physician Drug and Diagnosis Audit, there were no recorded mentions of Coreg 50 mg being written as a single dose.</p>

Oravig (miconazole) tablet	Strength 50 mg	Usual Dose: Apply one (1) tablet to the gum region once daily for 14 days
Failure Mode: Name confusion	Causes (could be multiple)	Rationale
(b) (4)		
<p>Actiq (fentanyl citrate) trouche/lozenge</p> <p>200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg</p> <p>200 mcg (one trouche) consumed over 15 minutes, wait 15 minutes if needed consume a second unit over 15 minutes</p>	<p><i>Orthographic similarities</i></p> <p>The letters ‘Or-’ can look similar to ‘Ac-’ when scripted</p> <p><i>Product characteristic similarities</i></p> <p>Overlapping route of administration (oral)</p> <p>Potential for overlapping dose (one)</p> <p>Potential for achievable dose (200 mg)</p> <p>Similar dosage forms (tablet/capsule)</p>	<p>Orthographic and product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>The upstroke of the letter ‘t’ in Actiq differentiate the two names when scripted</p> <p>While both products can be taken as a one time dose, Oravig is taken as a one time dose once a day over 14 consecutive days.</p> <p>Actiq prescriptions will likely have supplemental information such as how to repeat the dose, as needed, not to exceed 4 units a day, etc.</p>

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22404	ORIG-1	BIOALLIANCE PHARMA	Lauriad (miconazole (b) (4) tablet)

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/s/

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