CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205175Orig1s000

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--Final

Date:	September 24, 2013
Reviewer:	Carlos M Mena-Grillasca, RPh, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, MS, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Ecoza (Econazole Nitrate) Foam, 1%
Application Type/Number:	NDA 205175
Applicant/Sponsor:	AmDerma Pharmaceuticals, LLC
OSE RCM #:	2013-834

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

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Ecoza is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Ecoza, acceptable in OSE Review 2013-320 dated April 29, 2013.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2013-320. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded one new name ([(b) (4)]***), thought to look or sound similar to Ecoza and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with [(b) (4)]*** and lead to medication errors. This analysis determined that the name similarity between Ecoza and [(b) (4)]*** was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of September 23, 2013.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Ecoza, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Ecoza, 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 Dermatology and Dental Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

4 REFERENCES

1. **Mena-Grillasca, C. Ecoza: Proprietary Name Review (NDA 205175; RCM 2013-320).** Silver Spring (MD): Food and Drug Administration, Division of Medication Error Prevention and Analysis (US); 2013 April 29.

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/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?)*

   USAN Stems List contains all the recognized USAN stems.

4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: FMEA Table

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
1.	(b) (4)		

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

/s/

CARLOS M MENA-GRILLASCA
09/24/2013

LUBNA A MERCHANT
09/24/2013

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:	April 29, 2013
Reviewer:	Carlos M Mena-Grillasca, RPh, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, MS, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Ecoza (Econazole Nitrate) Foam, 1%
Application Type/Number:	NDA 205175
Applicant/Sponsor:	AmDerma Pharmaceuticals, LLC
OSE RCM #:	2013-320

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ecoza, 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 January 29, 2013 proprietary name submission.

- Active Ingredient: Econazole Nitrate
- Indication of Use: Treatment of interdigital tinea pedis [redacted (b) (4)]
- Route of Administration: Topical
- Dosage Form: Foam
- Strength: 1 %
- Dose and frequency: Apply topically to affected area once daily for four weeks.
- How Supplied: 10 grams, 70 grams [redacted (b) (4)] in aluminum cans pressurized with a butane propellant.
- Storage: [redacted (b) (4)] excursions permitted to 15º-30ºC (59º-86 ºF)
- Intended pronunciation: ē-koh-zah

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 Dermatology and Dental Products 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

The February 7, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicates in their submission that the name was selected for marketing reasons and for the ability to obtain trademark protection.

This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed product nor did it appear to sound or look similar to any currently marketed products or products in the pipeline. Seventy-nine participants interpreted the name correctly (inpatient n=26; outpatient n=33; voice n=20). Four participants in the voice study misinterpreted the 'z' sound for an 's'. Four participants in the inpatient study misinterpreted the letter 'E' for a 'T'. Only one participant in the outpatient study misinterpreted the letter 'z' for an 'x'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Stage of Review

In response to the OSE, March 26, 2013 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

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, Ecoza. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Ecoza, identified by the primary reviewer, and the Expert Panel Discussion (EPD). Table 1 also includes the names identified from the External Study by AmDerma not identified by DMEPA and that require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and AmDerma)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Aci-jel	FDA	Econazole	FDA, Amderma	Lovaza	FDA, Amderma
Acunol	FDA	(b) (4) ***	FDA	Moxeza	Amderma
Acusil	FDA	Ecosave	Amderma	Onglyza[1]	Amderma
Aczone	FDA	Ecotrin	FDA, Amderma	Prozac	FDA
Albenza	Amderma	Ecovia	FDA	Qutenza	Amderma
Alora	FDA	Elocon	FDA	Relenza	Amderma
Avinza	Amderma	(b) (4) ***	FDA	Suprenza	Amderma
Beconase[2]	Amderma	Encora	FDA	(b) (4) ***	FDA

[1] Name submitted by AmDerma as "Oglynza"; however, the correct spelling is Onglyza.

[2] Name submitted by AmDerma as "Beconaze"; however, the correct spelling is Beconase.

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Colazal	Amderma	Icaps	FDA	Vidaza	Amderma
Cozaar[3]	Amderma	Icar	FDA	Zolinza	Amderma
Doca	FDA	Icar-c	FDA		
Eckol	Amderma	Inova	FDA		
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Akurza	FDA	Victoza[4]	FDA, Amderma		
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Aconia	FDA	Ecoza	FDA	Epogen	FDA
Acova	FDA	Ecozar	FDA	Evoxac	FDA

Our analysis of the 42 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the names will pose a risk of confusion as described in Appendices D and E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Dermatology and Dental Products via e-mail on April 1, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on April 2, 2013, they stated no additional concerns with the proposed proprietary name, Ecoza.

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 Janet Anderson, OSE project manager, at 301-796-0675.

[3] Name submitted by AmDerma as "Cozar"; however, the correct spelling is Cozaar.

[4] Name submitted by AmDerma as "Victozar"; however, the correct spelling is Victoza.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your January 29, 2013 submission 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. [1]

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 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.[2]

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

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

[2] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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).

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	• 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	• 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	• 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 gather 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.[1] When

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

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 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 posses 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Ecoza	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'E'	C, f, I, T	Any vowel
Lower case 'e'	a, i, l, o, u, p	Any vowel
Lower case 'c'	a, e, i, l	g
Lower case 'o'	a, c, e, u	Any vowel
Lower case 'z'	c, e, g, n, m, q, r, s, v, y	s
Lower case 'a'	el, ci, cl, d, o, u	Any vowel
Letter Strings		
ec	u	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Ecoza Study (Conducted on February 8, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Ecoza UAD Medication Order: #1	Ecoza Use as Directed Disp. #1
Outpatient Prescription: Ecoza apply U to affected area qday U	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 3/25/2013

192 People Received Study

93 People Responded

Study Name: Ecoza

Total	31	28	34	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
DECOZA	0	1	0	1
ECHOSA	0	1	0	1
ECORA	1	0	0	1
ECOSA	0	3	0	3
ECOSSA	0	1	0	1
ECOXA	0	0	1	1
ECOZA	26	20	33	79
ECOZAR	0	1	0	1
EKOZA	0	1	0	1
TCOZA	4	0	0	4

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 Ecoza	Failure preventions
1.	**Aci-jel**	Acetic acid, Glacial, Oxyquinoline Sulfate, Ricinoleic Acid	Look	This product is discontinued with no generic equivalent available. However, a branded equivalent product, Acid Jelly, is available.
2.	**Aconia**	Acontinum Napellus	Look	Name found on Natural Medicines database. No product information available in major drug references (i.e. Drugs@FDA, Clinical Pharmacology, Facts and Comparison, Red Book, RxList, Walgreens, CVS, DailyMed, etc.).
3.	**Albenza**	Albendazole	AmDerma	Name lack significant orthographic similarities.
4.	**Beconase**	Beclomethasone Dipropionate Monohydrate	AmDerma	Name lack significant orthographic similarities.
5.	**Colazal**	Balsalzide Disodium	AmDerma	Name lack significant orthographic similarities.
6.	**Doca**	Desoxycorticosterone Acetate	Look	Discontinued product with no generic equivalent available.

No.	Proprietary Name	Active Ingredient	Similarity to Ecoza	Failure preventions
7.	**Eckol**	n/a	AmDerma	Name lack significant orthographic similarities.
8.	n/a	**Econazole nitrate**	Look, AmDerma	Name lack significant orthographic similarities.
9.	(b) (4)			
10.	**Ecosave**	Triclosan	AmDerma	Family name for a product line of over the counter antibacterial hand soaps (i.e. Ecosave Japanese Cherry Blossom, Ecosave Lavender, Ecosave Grapefruit and Lemongrass). A prescription would need to include specific information to identify the product.
11.	**Ecovia**	Remacemide	Look	Name found on Facts and Comparison database for an orphan drug. This name is not available in any major drug reference and specific product information is not available.
12.	**Ecoza**	Econazole Nitrate	Look and Sound	Proposed proprietary name under evaluation in this review.
13.	**Ecozar**	Losartan Potassium	Look and Sound	Name found on Micromedex and LexiComp. International brand name for Losartan in the Philippines.
14.	(b) (4)			
15.	**Encora**	Multivitamins	Look	Discontinued product with no apparent generic equivalent available. Name found on RedBook Online as 'deactivated' and in Clinical Pharmacology under monograph for many vitamin products. No specific product information available.
16.	**Epogen**	Epoietin Alfa	Look and Sound	Name lack significant orthographic and phonetic similarities.
17.	**I Caps**	Multiple	Look	Family name for a product line of over the counter 'eye vitamins' (i.e. I Caps MV Multivitamin, I Caps Lutein & Zeaxanthin, I Caps Areds Formula tablets, I Caps Areds Formula softgels, I Caps Lutein & Omega-3). A prescription would need to include specific information to identify the product.

No.	Proprietary Name	Active Ingredient	Similarity to Ecoza	Failure preventions
18.	**Icar** **Icar-C**	Multiple	Look	Family name for a product line of multivitamins (i.e. Icar Pediatric Chewables, Icar Pediatric Suspension, Icar Prenatal Rx Tablet, Icar Prenatal Tablet, Icar-C Plus Tablet, Icar-C Tablet). A prescription would need to include specific information to identify the product.
19.	**Inova**	Benzoyl Peroxide and Vitamin E	Look	Family name for a product line of acne products (i.e. Inova 4%, Inova 8%, Inova ACT 4/1, Inova ACT 8/2). A prescription would need to include specific information to identify the product.
20.	**Moxeza**	Moxifloxacin Hydrochloride	AmDerma	Name lack significant orthographic similarities.
21.	**Onglyza**	Saxagliptin	AmDerma	Name lack significant orthographic similarities.
22.	**Qutenza**	Capsaicin	AmDerma	Name lack significant orthographic similarities.
23.	**Relenza**	Zanamivir	AmDerma	Name lack significant orthographic similarities.
24.	**Suprenza**	Phentermine Hydrochloride	AmDerma	Name lack significant orthographic similarities.
25.	(b) (4)			
26.	**Vidaza**	Azacitidine	AmDerma	Name lack significant orthographic similarities.
27.	**Zolinza**	Vorinostat	AmDerma	Name lack significant orthographic similarities.

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.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
28.	**Acova** (Argatroban) Injection, 250 mg/2.5 mL Dosage: Adult: 0.5-10 mcg/kg/min intravenously as a continuous infusion. OR 150-350 mcg/kg intravenous bolus and 15-30 mcg/kg/min intravenously as a continuous infusion. *Note: Name found on Drugs@FDA database. However, NDA 020883 is active under the generic name, Argatroban. The name Acova is not available in major drug references (i.e. Clinical Pharmacology, Facts and Comparison, Red Book, RxList, Walgreens, CVS, DailyMed, etc..*	Orthographic: Both root names have the same number of letters. The letter 'A' may look like the letter 'E' when scripted. Both names share the letter string 'co' and the letter 'a' in the same positions. The letter 'v' may look like the letter 'z' when scripted. Phonetic: Both names have three syllables. First syllable: Both have a single vowel sound. Second: Both have the same 'co' sound. Third: Both end in the same vowel sound. Strength: Both are single strength products and thus no strength is required on a prescription.	Phonetic: Although both names begin with a vowel sound, the 'a' vs. 'e' sounds are different. On the third syllable the initial 'v' sound is labio-dental vs. the 'z' sound is alveolar. Dose, route of administration, and frequency: Apply to affected areas once daily or UAD vs. xx mcg by intravenous bolus or continuous infusion

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
29.	**Acunol** (nickel sulfate, potassium bromide, sodium bromide, zinc sulfate anhydrous, and sulfur) Tablets, Dosage: ½ to 4 tablets orally twice daily	Orthographic: Both names have a similar number of letters (6 vs. 5). The capital letter 'A' may look like the capital letter 'E' when scripted. Both names share the letter 'c' in the same position. The letter string 'no' may look like 'za' when scripted. Strength: Both are single strength products and thus no strength is required on a prescription.	Orthographic: Acunol ends with an up stroke letter 'l' that is not present in Ecoza, and might give the names a different shape when scripted. Dosage: Apply to affected area or UAD vs. xx tablets
30.	**Acusil** (Methylsulfonyl Methane, Tumeric extract, White willow extract, Boswellia Serrata extract, Ginger extract) Capsules, 500 mg/200 mg/ 100 mg/ 150 mg/150 mg Dosage: 1 capsule orally in the morning and 1 capsule in the evening with 8 ounces of water.	Orthographic: Both names have a similar number of letters (6 vs. 5). The capital letter 'A' may look like the capital letter 'E' when scripted. Both names share the letter 'c' in the same position. The letter 's' may look like the letter 'z' and the letter string 'il' may look like the letter 'a' when scripted. Strength: Both are single strength products and thus no strength is required on a prescription.	Orthographic: Acusil ends with an up stroke letter 'l' that is not present in Ecoza, and might give the names a different shape when scripted. Dosage: Apply to affected area or UAD vs. 1 capsule

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
31.	**Aczone** (Dapsone) Gel, 5% Dosage: Apply a thin layer to the acne affected areas twice daily.	Orthographic: Both names have a similar number of letters (6 vs. 5). The capital letter 'A' may look like the capital letter 'E' when scripted. Both names share the letters 'c' and 'z' in the same and similar positions, respectively. Both names share the letter 'o'. Strength: Both are single strength products and thus no strength is required on a prescription. Dosage: Both products can be prescribed 'UAD'. Route of administration: Both products are used topically	Orthographic: The position of the letter 'o' preceding the letter 'z' in Ecoza vs. after the letter 'z' in Aczone make the ending letter string 'one' looks different than the ending letter string 'a'.

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
32.	**Akurza** (Salicylic Acid) Cream, 6% Lotion, 6% Dosage: Apply to affected area once to twice daily. *Note: Product is discontinued but generic equivalents are available.*	Phonetic: Both names have three syllables. First syllable: Both have a single vowel sound. Second: Both begin with a similar 'k' sound. Third: Both end in the same 'za' sound. Strength: Both are single strength products and thus no strength is required on a prescription. Dosage: Both products can be prescribed 'UAD'. Route of administration: Both products are used topically	Phonetic: Although both names begin with a vowel sound, the 'a' vs. 'e' sounds are different. On the second syllable the final 'r' sound in Akurza is not present in Ecoza. Dosage forms: Ecoza is only available in one dosage form (foam) and may be omitted from a prescription, whereas Akurza is available in two dosage forms (cream and lotion) and a dosage from would be required on a prescription. In addition, the dosage forms between the products do not overlap.
33.	**Alora** (Estradiol) Transdermal System, 0.25 mg/day 0.05 mg/day 0.075 mg/day 0.1 mg/day Dosage: Apply one patch twice weekly.	Orthographic: Both names have the same number of letters. The capital letter 'A' may look like the capital letter 'E' when scripted. Both names share the letters 'o' and 'a' in the same positions. The ending letter string 'ora' may look like the corresponding letter string 'oza' when scripted. Dosage: Both products can be prescribed 'UAD'. Route of administration: Both products are used topically	Orthographic: Alora has an additional up stroke letter 'l' in the second position that is not present in Ecoza and gives the names a different shape when scripted. Strength: Ecoza is a single strength product vs. Alora is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose. Although there is numerical similarity between strengths (0.1 vs. 1) the units of measure are different (mg/day or mg vs. %).

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
34.	**Avinza** (Morphine Sulfate) Extended-release Capsules, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg Dosage: Initiate at 30 mg orally once daily. Adjust the dose to provide adequate analgesia and minimize adverse reactions. Maximum daily dose is 1600 mg/day.	Orthographic: Both names have a similar number of letters (6 vs. 5). The capital letter 'A' may look like the capital letter 'E' when scripted. Both names share the letter string 'za' in the same position. Frequency of administration: Both products are dosed once daily.	Orthographic: The middle portions of the names ('in' vs. 'o') look different when scripted. Strength: Ecoza is a single strength product vs. Avinza is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. Dosage: Apply to affected area or UAD vs. XX capsule or XX mg
35.	**Cozaar** (Losartan Potassium) Tablets 25 mg, 50 mg, 100 mg Dosage: 25 to 100 mg orally once daily or in two divided doses.	Phonetic: The first syllable 'co' in Cozaar is the same as the second syllable 'co' in Ecoza. The second syllable 'zar' in Cozaar sounds like the third syllable 'za' in Ecoza. Frequency of administration: Both products may be dosed once daily.	Phonetic: Ecoza has three syllables vs. 2 syllables in Cozaar. The first syllable 'e' in Ecoza is not present in Cozaar and help differentiate the names when spoken. Dose: Apply to the affected area or UAD vs. xx tablets or xx mg

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
36.	**Ecotrin** (Aspirin) Tablets 81 mg, 325 mg Dosage: Adults and children 12 years of age and older: Low strength: 4 to 8 tablets orally every 4 hours Regular strength: 1 to 2 tablets every 4 hours	Orthographic: Both names begin with the same letter string 'Eco'.	Orthographic: Ecotrin has un upstroke letter 't' that is not present in Ecoza, which gives the names a different shape when scripted. Ecotrin has 7 letters vs. 5 letters in Ecoza, which makes the ending letters strings different 'trin' vs. 'za'. Strength: Ecoza is a single strength product vs. Ecotrin is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. Dose: Apply to the affected area or UAD vs. xx tablets or xx mg
37.	**Elocon** (Mometasone Furoate) Cream, 0.1% Lotion, 0.1% Ointment, 0.1% Dosage: Apply topically to affected areas once daily.	Orthographic: Both names have a similar number of letters (6 vs. 5). Both names begin with the letter 'E' and share the letter 'o' in the third position. The letter string 'co' in Elocon may look like the corresponding letter string 'za' in Ecoza. Strength: Both are single strength products and thus no strength is required on a prescription. In addition, there is numerical similarity in strength (0.1% vs. 1%) Dosage: Both products can be prescribed 'UAD'. Route and frequency of administration: Both products are applied topically once daily	Orthographic: Elocon has an additional up stroke letter 'l' in the second position that is not present in Ecoza and gives the names a different shape when scripted. The ending letter 'n' makes Elocon appear longer when scripted. Dosage forms: Ecoza is only available in one dosage form (foam) and may be omitted from a prescription, whereas Elocon is available in three dosage forms (cream, ointment, and lotion) and a dosage from would be required on a prescription. In addition, the dosage forms between the products do not overlap.

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
38.	**Evoxac** (Cevimeline Hydrochloride) Capsules, 30 mg Dosage: 30 mg orally three times daily	Orthographic: Both names have a similar number of letters (6 vs. 5). Both names begin with the capital letter 'E' and share the letters 'o' and 'a' in the same positions. Phonetic: Both names have 3 syllables. First syllable: Both have the same single vowel sound 'e'. Second: Both end with the same 'o' sound. Third: Both contain the vowel 'a' sound. Strength: Both are single strength products and thus no strength is required on a prescription.	Phonetic: Second syllable: Begins with an affricative labio-dental 'v' sound in Evoxac vs. a plosive velar 'k' sound in Ecoza. Third syllable: End with an additional 'k' sound in Evoxac that is not present in Ecoza. Dose: Apply to the affected area or UAD vs. xx tablets or xx mg
39.	**Lovaza** (Omega-3-acid ethyl esters) Capsules Dosage: 4 grams per day taken as a single 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules twice daily)	Orthographic: Both names have a similar number of letters (6 vs. 5). The letters 'L' and 'E' may look similar if scripted in lower case. Both names share a letter 'o' and end in the letter string 'za'. Strength: Both are single strength products and thus no strength is required on a prescription. Frequency of administration: Both products may be administered once daily.	Orthographic: The letters 'ov' in Lovaza look different than the corresponding letters 'co' and may help differentiate the names. Dose: Apply to the affected area or UAD vs. xx grams or xx capsules

No.	**Proposed name:** Ecoza **Dosage Form:** Foam **Strength:** 1% **Usual Dose:** Apply topically to affected area once daily for four weeks.	**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**
40.	**Prozac** (Fluoxetine Hydrochloride) Capsules, 10 mg, 20 mg, 40 mg Dosage: 10 to 80 mg orally daily in a single dose or two divided doses.	Orthographic: Both names have a similar number of letters (6 vs. 5). Both names share the letter string 'oza' in the same position. Frequency of administration: Both products may be administered once daily.	Orthographic: The capital letter 'P' in Prozac looks different than the capital letter 'E' in Ecoza. Strength: Ecoza is a single strength product vs. Prozac is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. Dose: Apply to the affected area or UAD vs. xx grams or xx capsules
41.	**Victoza** Liraglutide (rDNA origin) Injection 18 mg/3 mL (6 mg/mL) Pre-filled pen deliver doses of 0.6 mg, 1.2 mg, and 1.8 mg Dosage: Initiate at 0.6 mg by subcutaneous injection once daily for one week, and then increase the dose to 1.2 mg or 1.8mg daily.	Phonetic: Both names have 3 syllables. Second: Both begin with a plosive sound ('t' vs. 'k') and both end with the same 'o' sound. Third: Both have the same 'za' sound. Strength: Both are single strength products and thus no strength is required on a prescription. Frequency of administration: Both products are administered once daily.	Phonetic: The first syllable in the names sound different ('Vic' vs. 'E') and help differentiate the names when spoken. Dose: Apply to the affected area or UAD vs. xx mg

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