

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**204153Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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

**Proprietary Name Review**

Date: April 11, 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: Luzu (Luliconazole)  
Cream, 1%

Application Type/Number: NDA 204153

Applicant/Sponsor: Medicis Pharmaceuticals Corporation

OSE RCM #: 2013-182

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

## CONTENTS

1	INTRODUCTION .....	1
1.1	Product Information.....	1
2.2	Safety Assessment.....	1
3	CONCLUSIONS.....	3
3.1	Comments to the Applicant.....	3
4	REFERENCES .....	4
	APPENDICES .....	7

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Luzu, 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 11, 2013 proprietary name submission.

- Active Ingredient: Luliconazole
- Indication of Use: Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by *Trichophyton rubrum*, (b) (4) or *Epidermophyton Floccosum*, in patients 18 years of age and older.
- Route of Administration: Topical
- Dosage Form: Cream
- Strength: 1 %
- Dose and frequency:
  - Tinea pedis: Once daily application for 2 weeks
  - Tinea cruris and Tinea corporis: Once daily application for 1 week
- How Supplied: 2 gram tubes (physician samples), 30 and 60 gram tubes.
- Storage: 15-30°C (59-86°F)
- Intended pronunciation: lü-zü

## 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 January 24, 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 derived from luliconazole.

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

Fifty-eight practitioners participated in DMEPA’s prescription studies. Thirty-three interpreted the name correctly (inpatient n=13; outpatient n=13; voice n=7). The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Nine participants in the voice study misinterpreted the ‘z’ for a ‘v’ sound and four participants misinterpreted the ‘l’ for a ‘n’ sound. Two participants in the outpatient study misinterpreted the letter ‘L’ for a ‘C’. 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, January 25, 2013 e-mail, the Division of Dermatology and Dental Products (DDDP) indicated that the team has no preliminary concerns to the proposed name. (b) (4)

### 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, Luzu. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Luzu, identified by the primary reviewer, the Expert Panel Discussion (EPD), and External Study (b) (4)

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, FDA Name Simulation Studies, (b) (4)**

Look Similar					
Name	Source	Name	Source	Name	Source
Baza	(b) (4)	Logen	FDA	Lunesta	(b) (4)
Ceenu	FDA	Lonox	FDA	Lustra	FDA
Fluzone	(b) (4)	Lopid	FDA	Luvox	FDA and (b) (4)
Fuzeon	FDA	Loqua 50	FDA	Luxiq	(b) (4)
(b) (4)	FDA	Loraz	(b) (4)	Luzerne	FDA
Lasix	FDA	Lorol	FDA	Tara-30	FDA
Levothroid	(b) (4)	Loso Prep	FDA	Vanos	FDA
Lezena	FDA	Lovaza	(b) (4)	Zalole	FDA
Lofed	FDA	Lugol’s solution	FDA		
Sound Similar					
Name	Source	Name	Source	Name	Source
Lazanda	FDA				
Look and Sound Similar					
Name	Source	Name	Source	Name	Source

Lozol	FDA and (b) (4)	Lupron	FDA	Luzu	FDA
-------	-----------------	--------	-----	------	-----

Our analysis of the 30 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none names will not pose a risk of confusion as described in Appendices D and E.

**2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review**

DMEPA communicated our findings to the Division of Dermatology and Dental Products via e-mail on March 8, 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 March 11, 2013, they stated concurrence with our determination of acceptable for the proposed name Luzu.

**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.

**3.1 COMMENTS TO THE APPLICANT**

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. If any of the proposed product characteristics as stated in your January 11, 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](http://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](http://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](http://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](http://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](http://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](http://www.lexi.com))**

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

**15. Medical Abbreviations ([www.medilexicon.com](http://www.medilexicon.com))**

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

**16. CVS/Pharmacy ([www.CVS.com](http://www.CVS.com))**

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

**17. Walgreens ([www.walgreens.com](http://www.walgreens.com))**

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

**18. Rx List ([www.rxlist.com](http://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](http://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.<sup>1</sup>

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.<sup>2</sup>

---

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

<sup>2</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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

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

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

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

### **1. Database and Information Sources**

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

### **2. Expert Panel Discussion**

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

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

### **3. FDA Prescription Simulation Studies**

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

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

#### 4. Comments from Other Review Disciplines

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

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

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

#### 5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>3</sup> 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 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

---

<sup>3</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

***“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.

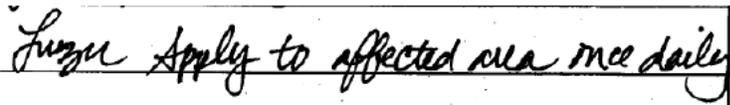
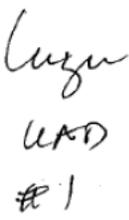
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, Luzu	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'L'	h, C, Z, S, T, J, V	N, W
Lower case 'l'	b, e, s, A, P, i	N, W
Lower case 'u'	a, n, v, ee, ii	Any vowel
Lower case 'z'	c, e, g, n, m, q, r, s, v, y	s
Letter Strings		
-lu	-bi	--

**Appendix C:** Prescription Simulation Samples and Results

**Figure 1. Luzu Study (Conducted on January 24, 2013)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Luzu Use as Directed Disp. #1</p>
<p><u>Outpatient Prescription:</u></p> 	

**Aggregate Report**  
As of Date 2/21/2013

192 People Received Study  
58 People Responded

Study Name: Luzu

Total	21	19	18	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CUZU	0	0	2	2
FIZU	1	0	0	1
LIZU	1	0	0	1
LOOVOO	0	1	0	1
LUAZU	1	0	0	1
LUOZIC	1	0	0	1
LUOZU	3	0	0	3
LUVU	0	5	0	5
LUVUD	0	1	0	1
LUVUE	0	1	0	1
LUZA	0	0	1	1
LUZER	0	0	1	1
LUZIC	0	0	1	1
LUZRI	1	0	0	1
LUZU	13	7	13	33
NEUVI	0	1	0	1
NEUZU	0	1	0	1
NUVE	0	1	0	1
NUVU	0	1	0	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Luzu	Failure preventions
1.	<b>Baza</b>	Multiple	Look	Family name for a product line of over the counter topical products (i.e. Baza Antifungal, Baza Clear, Baza Clean & Protect Odor Control, Baza Protect, and Baza Cleanse & Protect.). A prescription would need to include specific information to identify the product.
2.	<b>Fluzone</b>	Influeza A Virus Antigen	(b) (4)	Name lack significant orthographic and phonetic similarities.
3.	(b) (4)	Elvitegravir, Cobicistat, Emtricitabine, and Tenofovir disoproxil	Look	Secondary name submitted for NDA 203100. Product approved under the name Stribild.
4.	<b>Levothroid</b>	Levothyroxine Sodium	(b) (4)	Name lack significant orthographic and phonetic similarities.
5.	<b>Lezena</b>	n/a	Look	Name reported by a Safety Evaluator from USPTO database. Unable to reproduce this search result in any major drug reference, including USPTO.
6.	<b>Lofed</b>	n/a	Look	Name found in Red Book with no additional information available. This name is not available in any major drug reference and specific product information is not available.
7.	<b>Logen</b>	Atropine Sulfate and Diphenoxylate Hydrochloride	Look	ANDA 088962 has an application status of Withdrawn FR Effective date of 3/18/1996.
8.	<b>Loqua-50</b>	n/a	Look	Name found in Red Book with no additional information available. This name is not available in any major drug reference and specific product information is not available.
9.	<b>Loraz</b>	Lorazepam	(b) (4)	Three ANDAs associated with this product are Withdrawn FR Effective. ANDA 070200 on 6/5/1990; ANDA 070201 and ANDA 070202 on 6/7/1990.
10.	<b>Lorol</b>	n/a	Look	Name found in Red Book with no additional information available. This name is not available in any major drug reference and specific product information is not available.

11.	<b>LoSo Prep</b>	Magnesium Citrate; Bisacodyl	Look	Name found in Red Book online. This product is an OTC colon cleansing kit containing magnesium citrate powder for oral solution, 4 bisacodyl 5 mg tablets, and 1 bisacodyl 10 mg suppository. This name was found in Facts & Comparisons with limited information available. This name was not available in any other major drug database and specific product information is not available.
12.	<b>Lunesta</b>	Eszopiclone	(b) (4)	Name lack significant orthographic or phonetic similarities.
13.	<b>Luzerne</b>	Alfalfa	Look	Name found in Natural Medicines database for products containing Alfalfa. However, this name is not available in any major drug reference and specific product information is not available.
14.	<b>Luzu</b>	Luliconazole	Look and Sound	Proposed proprietary name under review.
15.	<b>Tara-30 Tara-8</b>	Phentermine	Look	The name Tara-30 was found in Red Book database with no additional information available. This name is not available in any major drug reference and specific product information is not available. The name Tara-8 was identified in Clinical Pharmacology database only and specific product information is not available.
16.	<b>Zalole</b>	n/a	Look	Name reported by a Safety Evaluator from Micromedex database. Unable to reproduce this search result in any major drug reference, including Micromedex.

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

No.	<p><b>Proposed name:</b> Luzu  <b>Dosage Form:</b>                      Cream  <b>Strength:</b> 1%  <b>Usual Dose:</b>                      Apply topically to affected area once daily for one or two weeks</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
17.	<p><b>CeeNU</b>                      (Lomustine) Tablets                      10 mg, 40 mg, 100 mg</p> <p><u>Dosage:</u>                      100- 130 mg/m<sup>2</sup> as a single oral dose every 6 weeks. All doses of CeeNU must be rounded to the nearest 10 mg by the prescriber.</p> <p>Doses subsequent to the initial dose should be adjusted (i.e. 70% or 50%) according to the hematologic response of the patient to the preceding dose.</p> <p>Pharmacist: Confirm the total dose prescribed by the physician can be obtained by determining the appropriate combination of capsule strengths. Only the appropriate number of CeeNU capsules required for the administration of a single dose should be dispensed.</p> <p>In order to provide the proper dose of CeeNU, patients should be aware that the prescribed dose may be made up of 2 or more different strengths and colors of capsules and that each strength must be dispensed separately. Inform patients that CeeNU is taken as a single oral dose and will not be repeated for at least 6 weeks. Daily use of the recommended dose may lead to toxicities and fatal outcomes.</p>	<p><u>Orthographic:</u></p> <p>Both names have a similar number of letters (5 vs. 4) and shape (if the letter string ‘nu’ is not capitalized) when scripted. The capital letter ‘C’ may look like the capital or lower case letters ‘L’ and ‘1’, respectively. The letter ‘ee’ may look like the letter ‘u’ when scripted. The letter ‘n’ may look like the letter ‘z’ if scripted without a down stroke. Both names end with the same letter ‘u’.</p> <p><u>Strength:</u></p> <p>Although Luzu is a single strength product, which may be omitted in a prescription, both products have numerical similarity on strength (10 mg vs. 1%).</p>	<p><u>Dose:</u></p> <p>Apply to affected area or UAD vs. xx mg or xx tabs</p> <p><u>Strength:</u></p> <p>Luzu is a single strength product vs. CeeNU is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in dose.</p> <p><u>Frequency of administration:</u></p> <p>Once daily vs. once every 6 weeks (under close monitoring and dose adjustment)</p>

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
18.	<b>Fuzeon</b> (Enfuvirtide) For Injection 90 mg/vial  <u>Dosage:</u> Adults: 90 mg by subcutaneous injection twice daily  Children 6 years through 16 years of age: 2 mg/kg up to a maximum dose of 90 mg by subcutaneous injection twice daily	<u>Orthographic:</u> The capital letter string 'F' may look like the capital letter 'L' when scripted. Both names share the same letter strings 'uz' in the same position.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.	<u>Orthographic:</u> Fuzeon has six letters vs. Luzu has four letters and look shorter when scripted. The capital letter 'F' is a cross stroke vs. the capital letter 'L' is not, which may help differentiate the names when scripted.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg
19.	<b>Lasix</b> (Furosemide) Tablets, 20 mg, 40 mg, 80 mg  <u>Dosage:</u> Adult: 10 to 600 mg orally daily or in two divided doses. Or every 6-8 hours.  Pediatric: 0.5 - 6 mg/kg orally daily or in two divided doses. Or every 6-8 hours.	<u>Orthographic:</u> Both names have a similar number of letters (5 vs. 4) and similar shape when scripted. Both names begin with the capital letter 'L' and the letters 'a' and 's' may look like the corresponding 'u' and 'z' when scripted. The ending letter string 'ix' may look like the ending letter 'u' when scripted.	<u>Strength:</u> Luzu is a single strength product vs. Lasix is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg or xx tab

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
20.	<b>Lazanda</b> (Fentanyl) Nasal Spray, 100 mcg/spray, 400 mcg/spray  <u>Dosage:</u> Initial dose is 100 mcg. Individually titrate to an effective dose, from 100 mcg to 200 mcg, to 400 mcg, and up to a maximum of 800 mcg, that provides adequate analgesia with tolerable side effects. Dose is a single spray into one nostril or a single spray into each nostril. No more than four doses per 24 hours. Wait at least 2 hours between doses of Lazanda.	<u>Orthographic:</u> Both names begin with the capital letter 'L' and share the letter 'z' in the same position. The letters 'a' may look like the corresponding letters 'u' when scripted.	<u>Orthographic:</u> Lazanda has 7 letters vs. Luzu has 4 letters and look shorter when scripted. Lazanda has an additional up stroke letter 'd' that help differentiate the names when scripted.  <u>Strength:</u> Luzu is a single strength product vs. Lazanda is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mcg or xx sprays  <u>Frequency of administration:</u> Once daily vs. wait at least 2 hours between doses (no more than 4 doses per 24 hours)  <u>Other:</u> Lazanda is available only through a restricted program called TIRP REMS Access program. Outpatients, healthcare professionals who prescribe for outpatients, pharmacies, and distributors are required to enroll in the program.

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
21.	<b>Lonox</b> (Atropine Sulfate and Diphenoxylate Hydrochloride) Tablets, 0.025 mg/2.5 mg  <u>Dosage:</u> Two tablets orally four times daily until initial control is achieved, after which the dosage may be reduced to meet individual requirements. Control may often be maintained with as little as 5 mg daily.	<u>Orthographic:</u> Both names have similar number of letters (5 vs. 4) and shape when scripted. Both names begin with the capital letter 'L' and the letters 'o' may look like the corresponding letters 'u' when scripted. The letter 'n' may look like a letter 'z' if scripted without a down stroke.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products may be administered once daily.	<u>Orthographic:</u> The ending letter 'x' in Lonox may help differentiate the names when scripted. In addition, if the letter 'z' is scripted with a down stroke, it may help differentiate the names when scripted.  <u>Dose:</u> Apply to affected areas or UAD vs. xx tab
22.	<b>Lopid</b> (Gemfibrozil) Tablets, 600 mg  <u>Dosage:</u> 600 mg orally twice daily before the morning and evening meals	<u>Orthographic:</u> Both names have similar number of letters (5 vs. 4). Both names begin with the capital letter 'L' and the letter 'o' may look like the letter 'u'. Both names have a down stroke in the same position ('p' vs. 'z' if scripted with a down stroke).  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.	<u>Orthographic:</u> Lopid has an additional up stroke letter 'd' in the last position, which gives the names a different shape when scripted.  <u>Dose:</u> Apply to the affected area or UAD vs. xx mg or 1 capsules

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
23.	<b>Lovaza</b> (Omega-3-acid ethyl esters) Capsules  <u>Dosage:</u> 4 grams per day taken as a single 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules twice daily)	<u>Orthographic:</u> Both names begin with the capital letter 'L'. The letters 'o', 'v', and 'a' in Lovaza may look like the corresponding letters 'u', 'z' (if not scripted with a down stroke), and 'u' in Luzu. In addition, both names contain the letter 'z'.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products may be administered once daily.	<u>Orthographic:</u> Lovaza has 6 letters vs. Luzu has 4 letters and look shorter when scripted. The common letter 'z' is in the third position in Luzu vs. in the fifth position in Lovaza, giving the names a different shape when scripted.  <u>Dose:</u> Apply to the affected area or UAD vs. xx grams or xx capsules

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
24.	<b>Lozol (Indapamide) Tablets, 1.25 mg</b>  <b>Dosage:</b> 1.25 to 5 mg orally once daily in the morning.	<u>Orthographic:</u> Both names have a similar number of letters (5 vs. 4). Both names begin with the capital letter ‘L’ and share the letter ‘z’ in the same position. The letters ‘o’ in Lozol may look like the letters ‘u’ in Luzu when scripted.  <u>Phonetic:</u> Both names have 2 syllables.  First syllable: Both begin with a consonant sound ‘l’ followed by a vowel sound.  Second syllable: Both begin with a consonant sound ‘z’ followed by a vowel sound.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products may be administered once daily.	<u>Orthographic:</u> Lozol has an additional up stroke letter ‘l’ in the last position, giving the names different shapes when scripted.  <u>Phonetic:</u> The vowel sound in both syllables sound different when spoken. The second syllable has an additional consonant sound ‘l’ at the end.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg or xx tab

No.	<p><b>Proposed name:</b> Luzu  <b>Dosage Form:</b>  Cream  <b>Strength:</b> 1%  <b>Usual Dose:</b>  Apply topically to affected area once daily for one or two weeks</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
25.	<p><b>Lugol's Solution</b></p> <p><b>Lugol's Strong Iodine</b>  (Iodine and Potassium Iodide) Solution,  <i>Unapproved drug</i></p> <p><u>Dosage:</u>  As an antiseptic: Apply to the areas that needing antiseptic</p> <p>Other unapproved indications:  Neonates: One drop in a full glass of water orally every 8 hours  Adults and children: 0.1 to 1 mL in a full glass of water orally three to four times daily</p>	<p><u>Orthographic:</u>  Both names begin with the letter string 'Lu'. Both names have a down stroke in the third position ('g' vs. 'z' if scripted with a down stroke). The letter 'o' in Lugol's may look like the corresponding letter 'u' in Luzu.</p> <p><u>Strength:</u>  Both are single strength products and thus no strength is required on a prescription.</p> <p><u>Route of administration:</u>  Both products may be applied topically.</p>	<p><u>Orthographic:</u>  The root name Lugol's has 6 letters vs. Luzu has 4 letters and looks shorter when scripted. Lugol's has an additional up stroke letter 'l' in the fifth position, giving the names different shapes when scripted. The ending letters 'ls' in Lugol's help differentiate the names when scripted.</p>

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
26.	<p><b>Lupron (Leuprolide Acetate) Injection, 5 mg/mL</b></p> <p><u>Dosage:</u></p> <p>The recommended starting dose is 50 mcg/kg/day administered as a single subcutaneous injection. If total downregulation is not achieved, the dose should be titrated upward by 10 mcg/kg/day. This dose will be considered the maintenance dose.</p> <p><b>Lupron Depot (Leuprolide Acetate for Depot Suspension) For Injection, 3.75 mg</b></p> <p><b>Lupron Depot Ped (Leuprolide Acetate for Depot Suspension) For Injection, 7.5 mg, 11.25 mg and 15 mg</b></p> <p><u>Dosage:</u></p> <p>Adult: 3.75 mg by intramuscular injection once monthly</p> <p>Pediatric: 7.5 mg, 11.25 mg or 15 mg administered as a single intramuscular injection every 4 weeks.</p>	<p><u>Orthographic:</u></p> <p>Both root names begin with the letter string ‘Lu’ followed by a down stroke (‘p’ vs. ‘z’ if scripted with a down stroke).</p> <p><u>Strength:</u></p> <p>Lupron and Luzu are single strength products and thus no strength is required on a prescription.</p> <p><u>Frequency of administration:</u></p> <p>Both products (Lupron and Luzu) are administered once daily.</p>	<p><u>Orthographic:</u></p> <p>Lupron has 6 letters vs. Luzu has 4 letters and look shorter when scripted. The ending ‘on’ in Lupron may help differentiate the names when scripted.</p> <p><u>Dose:</u></p> <p>Apply to affected areas or UAD vs. xx mg</p>

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
27.	<b>Lustra</b> Hydroquinone Cream USP, 4%  <b>Lustra-AF</b> Hydroquinone Cream USP, 4%  <u>Dosage:</u> Apply topically to affected area twice daily, morning and bedtime.	<u>Orthographic:</u> Both root names begin with the letter string 'Lu'. The letter 's' may look like the letter 'z' (if not scripted with a down stroke) when scripted.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Route of administration:</u> Both are topical products  <u>Dose:</u> Both products may be prescribed as 'UAD'.	<u>Orthographic:</u> Lustra has 6 letters vs. Luzu has 4 letters and look shorter when scripted. Lustra has an additional up stroke letter 't', which gives the names a different shape when scripted. The ending '-tra' in Lustra looks different than the ending 'u' in Luzu.
28.	<b>Luvox (Fluvoxamine Maleate)</b> Tablets, 25 mg, 50 mg, 100 mg  <u>Dosage:</u> Adults: 25 mg to 100 mg orally at bedtime. Maximum dose 300 mg/day; doses over 100 mg should be given in two divided doses.  Children: 25 mg to 50 mg orally at bedtime. Maximum dose 300 mg/day; doses over 50 mg should be given in two divided doses  <b>Luvox CR (Fluvoxamine Maleate) Extended-release Capsules, 100 mg and 150 mg</b>  <u>Dosage:</u> 100 mg to 300 mg orally at bedtime	<u>Orthographic:</u> Both root names have a similar number of letters (5 vs. 4) and shape when scripted (if the 'z' is not scripted with a down stroke). Both names begin with the letter string 'Lu' and the letters 'v' and 'o' may look like the corresponding letters 'z' (if not scripted with a down stroke) and 'o' when scripted.  <u>Frequency of administration:</u> Both products could be prescribed for once daily use.	<u>Orthographic:</u> The ending letter 'x' in Luvox may help differentiate the names when scripted. In addition, if the letter 'z' is scripted with a down stroke, it may help differentiate the names when scripted.  <u>Strength:</u> Luzu is a single strength product vs. Luvox is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg or xx tab

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
29.	<b>Luxiq</b> (Bethametasone Valerate) Foam, 0.12%  <u>Dosage:</u> Apply twice daily, morning and night, to the scalp	<u>Orthographic:</u> Both names have similar number of letters (5 vs. 4). Both names begin with the letter string 'Lu' and have a down stroke letter ('q' vs. 'z', if scripted with a down stroke).  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Route of administration:</u> Both are topical products  <u>Dose:</u> Both products may be prescribed as 'UAD'.	<u>Orthographic:</u> The down stroke letter 'q' is in the 5 <sup>th</sup> position in Luxiq vs. the down stroke letter 'z' is in the 3 <sup>rd</sup> position in Luzu (if scripted with a down stroke). Luzu with or without a down stroke letter 'z', provide for different shapes between the names to provide differentiation.

No.	<b>Proposed name:</b> Luzu <b>Dosage Form:</b> Cream <b>Strength:</b> 1% <b>Usual Dose:</b> Apply topically to affected area once daily for one or two weeks	<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
30.	<b>Vanos (Fluocinonide) Cream, 0.1%</b>  <u>Dosage:</u> Apply a thin film layer once or twice daily to the affected area.	<u>Orthographic:</u> Both names have similar number of letters (5 vs. 4). The capital letter ‘V’ could look like the capital letter ‘L’ when scripted. The letters ‘a’, ‘n’, and ‘o’ could look like the corresponding letters ‘u’, ‘z’ (if not scripted with a down stroke) and ‘u’ when scripted.  <u>Strength and Unit of measure:</u> Both are single strength products and thus no strength is required on a prescription. In addition, there is numerical similarity in the strength (0.1% vs. 1%) and the same unit of measure (%).  <u>Route of Administration:</u> Both products are for topical administration  <u>Frequency of administration:</u> Both products may be applied once daily.  <u>Dose:</u> Both products are apply to the affected area or UAD	<u>Orthographic:</u> None of the letters in the names overlap. Therefore, most of the letters must be scripted in a way that it would resemble the other product’s name. Additionally the ending letter string “nos” appears longer than the letter string ‘zu’ due to the presence of an additional letter.

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

/s/  
-----

LUBNA A MERCHANT on behalf of CARLOS M MENA-GRILLASCA  
04/11/2013

LUBNA A MERCHANT  
04/11/2013

CAROL A HOLQUIST  
04/11/2013