# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**022569Orig1s000**

# 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 Medication Error Prevention and Risk Management**

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|---|---|
| Date | June 09, 2011 |
| Application Type/Number: | NDA 022569 |
| Through: | Irene Z. Chan, Pharm.D., BCPS, Team Leader<br>Todd Bridges, RPh, Acting Deputy Director<br>Carol Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Morgan A. Walker, Pharm.D., M.B.A., Safety Evaluator<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name: | Lazanda (Fentanyl) Nasal Spray<br>100 mcg per spray<br>400 mcg per spray |
| Applicant: | Archimedes Development Limited |
| OSE RCM #: | 2011-1130 |

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

## 1 INTRODUCTION

This re-assessment of the proprietary name, Lazanda, is in anticipation of approval of NDA 022569 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Lazanda, acceptable in OSE Review 2010-2545, dated February 24, 2011.

## 2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We use the same search criteria outlined in OSE Review #2010-2545, for the proposed proprietary name, Lazanda. Since none of the proposed characteristics were altered, we did not evaluate previous names of concern. Our searches of the databases did not yield any new names thought to look or sound similar to Lazanda and represent a potential source of drug name confusion.

Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Lazanda, as of May 31, 2011.

## 3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Lazanda, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proposed proprietary name, Lazanda, 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 Anesthesia and Analgesia Products (DAAP) 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 Danyal Chaudhry, OSE Safety Regulatory Project Manager, at 301-796-3813.

## 4 REFERENCES


**1.** Holmes L. OSE Review #2010-2545: Proprietary Name Review for Lazanda. February 24, 2011.

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

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

USAN Stems List contains all the recognized USAN stems.

**4.** ***Division of Medication Error Prevention and Analysis proprietary name 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.

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/s/

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TODD D BRIDGES
06/09/2011
Also signing for Morgan Walker

CAROL A HOLQUIST
06/14/2011

**Department of Health and Human Services**

**Public Health Service**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Surveillance and Epidemiology**

| | |
|---|---|
| Date: | February 24, 2011 |
| Application Type/Number: | NDA 022569 |
| Through: | Irene Z. Chan, PharmD, BCPS, Acting Team Leader<br>Carol A. Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Loretta Holmes, BSN, PharmD, Safety Evaluator<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name: | Lazanda (Fentanyl) Nasal Spray<br>100 mcg per spray<br>400 mcg per spray |
| Applicant: | Archimedes Development Limited |
| OSE RCM #: | 2010-2545 |

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## EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Lazanda, for Archimedes Development Limited's Fentanyl Nasal Spray, 100 mcg or 400 mcg per spray. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Lazanda, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

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

## 1 BACKGROUND

### 1.1 INTRODUCTION

This review responds to a November 29, 2010 request from Archimedes Development Ltd. for assessment of the proposed proprietary name, Lazanda, regarding potential name confusion with other proprietary or established drug names in the usual practice settings and promotional concerns.

Additionally, the container labels, carton and insert labeling are being evaluated for their potential contribution to medication errors under separate cover (OSE Review 2010-2138).

### 1.2 REGULATORY HISTORY

The Applicant initially submitted the proposed proprietary name, (b) (4) (primary) for our assessment. However, our evaluation found this proposed name unacceptable because (b) (4) (b) (4) Additionally, DMEPA communicated to the Applicant in a teleconference on December 7, 2009, that the secondary name, (b) (4), was also considered unacceptable because (b) (4) Thus, the Applicant submitted the name, (b) (4) for our assessment. However, the name was withdrawn on April 7, 2010 and the proposed name, (b) (4) was submitted for our assessment. The name (b) (4) was found unacceptable because (b) (4) (see OSE Review 2010-1086, dated August 11, 2010). Subsequently, the Applicant submitted the proposed name, Lazanda, for our assessment.

This NDA is a 505(b)(2) application. The reference listed drug is Actiq (Fentanyl Citrate) Oral Transmucosal Lozenge (NDA 20747).

### 1.3 PRODUCT INFORMATION

Lazanda is the proposed proprietary name for Fentanyl Nasal Spray. Lazanda is an opioid analgesic and Schedule II controlled substance indicated only for the management of breakthrough cancer pain in patients, 18 years of age and older, who are already receiving and who are tolerant to regular opioid therapy for their underlying persistent cancer pain. Lazanda should be individually titrated to an effective dose that provides adequate analgesia and minimizes side effects. The initial dose to treat episodes of breakthrough cancer pain is always 100 mcg. Patients must wait at least 2 hours before treating another episode of breakthrough pain with Lazanda. No more than four doses per 24 hours is recommended. During titration, one dose of Lazanda may include administration of one or two sprays of the same dosage strength (100 mcg or 400 mcg). There are no clinical data to support the use of a combination of dose strengths to treat an episode.

Lazanda Nasal Spray delivers a spray of 100 mcL of solution containing 100 mcg or 400 mcg Fentanyl base. This enables doses of 100 mcg or 400 mcg to be administered using a single spray into one nostril

(1 spray) and 200 mcg or 800 mcg to be administered using a single spray into both nostrils (2 sprays). Lazanda will be supplied in bottles that deliver eight sprays after being primed. The nasal spray pump locks after eight sprays have been administered. Each bottle is supplied with a child-resistant storage container in which Lazanda should stored at all times. Store Lazanda at room temperature (15º to 30ºC).

# 2 METHODS AND MATERIALS

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

## 2.1 SEARCH CRITERIA

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

To identify drug names that may look similar to Lazanda, the DMEPA Safety Evaluators also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (one, lower case "d"), downstrokes (one potential downstroke letter, lower case "z"), cross strokes (one potential cross-stroke letter, lower case "z"), and dotted letters (none). Additionally, several letters in Lazanda may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA Safety Evaluators also consider these alternate appearances when identifying drug names that may look similar to Lazanda.

When searching to identify potential names that may sound similar to Lazanda, the DMEPA Safety Evaluators search for names with similar number of syllables (three), stresses (LA-zan-da, la-ZAN-da, or la-zan-DA), and placement of vowel and consonant sounds. Additionally, the DMEPA Safety Evaluators consider that pronunciation of parts of the name can vary (see Appendix B). The Applicant's intended pronunciation of the name is "la ZAN da". However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

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

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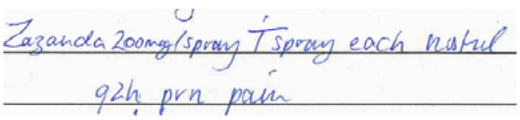
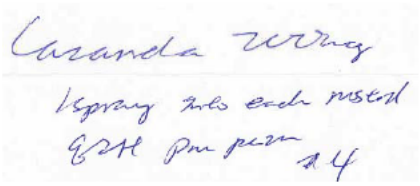
[1] Institute for Safe Medication Practices. Confused Drug Name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

**Figure 1. Lazanda Prescription Studies (conducted on December 10, 2010)**

| HANDWRITTEN REQUISITION MEDICATION ORDER | VERBAL PRESCRIPTION |
|---|---|
| Inpatient Medication Order:<br>  | "Lazanda 200 mcg spray<br>One spray into each nostril<br>every 2 hours as needed for<br>breakthrough pain" |
| Outpatient Prescription:<br>  | |

## 3 RESULTS

The following sections describe DMEPA's findings from the database searches, CDER Expert Panel Discussion, and FDA prescription analysis studies.

### 3.1 DATABASE AND INFORMATION SOURCES

The DMEPA searches yielded a total of 41 names as having some similarity to the name Lazanda.

Thirty-three of the 41 names were thought to look like Lazanda. These include Lozol, Caziant, Cozaar, Zegerid, Zavesca, Taztia XT, Coumadin, Lysteda, Lovenox, Zolinza, Zoladex, Lavandin, Loperamide, Synercid, Lysodren, Avandia, Canasa, Namenda, Lunesta, (b) (4), (b) (4), (b) (4), (b) (4), Larodopa, Lipitor, Liprofen, Capoten, Synalar, Zazole, Fazaclo, Losartan, Lucentis, and (b) (4). The remaining eight names, Latuda, Treanda, Laryssa, Loryna, Lialda, Lusedra, Lysteda, and Lovaza were thought to look and sound similar to Lazanda.

Additionally, DMEPA Safety Evaluators did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name as of February 11, 2011.

### 3.2 CDER EXPERT PANEL DISCUSSION

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

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

### 3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 26 practitioners responded. None of the practitioners interpreted the name correctly as "Lazanda". The remainder of the practitioners misinterpreted the drug name. None of the responses overlapped with any existing or proposed drug names. In the verbal studies, all responses were misspelled phonetic variations of the proposed name, Lazanda. However, we note the proposed name was pronounced "Lozanda" in the verbal prescription study and 10 practitioners responded with that spelling of the name. Additionally, we acknowledge the prescription studies for this name were sent out with the wrong product strength (200 mcg per spray). We realize that strengths can influence confirmation bias for names; however, 200 mcg is a strength available for other Fentanyl products. Therefore, we do not believe this negatively impacted the study results. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### 3.4 COMMENTS FROM THE DIVISION OF ANESTHESIA AND ANALGESIA PRODUCTS (DAAP)

#### 3.4.1 Initial Phase of Review

In response to the email sent to the Division of Anesthesia and Analgesia Products (DAAP) on December 7, 2010, the DAAP stated "we were fine with it".

#### 3.4.2 Midpoint of Review

On February 8, 2011, DMEPA notified DAAP via e-mail that we had no objections to the proposed proprietary name, Lazanda. Per e-mail correspondence from DAAP on February 11, 2011, the Division stated "We don't have any concerns with the name".

### 3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in identification of three additional names, Sufenta, Leventa, and Zensana which were thought to look similar to Lazanda and represent a potential source of drug name confusion.

The primary safety evaluator noted there was one misidentified name, (b) (4), found in the database searches in Section 3.1 above. It was determined this name should have been (b) (4), which was evaluated instead of (b) (4)

Thus, we evaluated a total of 44 names: 41 identified in Database and Information Sources (Section 3.1) and three identified in this section by the primary Safety Evaluator.

## 4 DISCUSSION

This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

### 4.1 PROMOTIONAL ASSESSMENT

DDMAC evaluated the name Lazanda from a promotional perspective and determined the name was acceptable. The Division of Anesthesia and Analgesia Products and the Division of Medication Error Prevention and Analysis concurred with this assessment.

### 4.2 SAFETY ASSESSMENT

In total, 44 names were identified as potential sources of name confusion with the proposed proprietary name, Lazanda. DMEPA did not identify other aspects of the name that could function as a source of error. Twenty-five of the 44 names were eliminated for the following reasons: Eighteen names lack orthographic and/or phonetic similarity, one is a discontinued product with no generic equivalents, one is a product used in pharmaceutical compounding, one is a veterinarian drug product, and four are names that have never been marketed (see Appendices D through H).

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with the remaining 19 names and lead to medication errors.

This analysis determined that the name similarity between Lazanda and these 19 products is unlikely to result in medication errors for the reasons presented in Appendices I and J.

## 5 CONCLUSIONS AND RECOMMENDATIONS

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

We consider this a final review, however, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change. The Applicant will be notified via letter from DMEPA.

### 5.1 COMMENTS TO THE APPLICANT

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

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

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

## 6 REFERENCES


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

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

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

   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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

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

   Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

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 requests***

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

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

   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)***

   Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

   Provides information regarding patent and trademarks.

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

   Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

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

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

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

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

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

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolph's Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

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

List contains all the recognized USAN stems.

***14. Red Book Pharmacy's Fundamental Reference***

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

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

A web-based searchable version of the Drug Information Handbook.

***16. Medical Abbreviations Book***

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

## Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

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

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its Safety Evaluators to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA Safety Evaluators consider the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA Safety Evaluators consider the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA Safety Evaluators also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA Safety Evaluators apply expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA Safety Evaluators compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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

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

**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<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name<br>Upstrokes<br>Down strokes<br>Cross-stokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

Lastly, the DMEPA Safety Evaluators also consider 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 Safety Evaluators conduct searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA Safety Evaluators use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA Safety Evaluators review the USAN stem list to determine if any USAN stems

are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

### 2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) Safety Evaluators and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

### 3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

### 4. Comments from the OND review Division or Generic drugs

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

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

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

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and

identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names 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.

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

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

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

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

**Appendix B: Letters with possible orthographic or phonetic misinterpretation**

| Letters in proposed name "Lazanda" | When scripted may appear as: | When spoken may be interpreted as: |
|---|---|---|
| Capital 'L' | Z, S, T | |
| lower case 'l' | b,e, s, i | Any vowel |
| lower case 'a' | el, ci, cl, d, o, u | Any vowel |
| lower case 'z' | c, e, g, n, m, q, r, s, v | c, s, x |
| lower case 'a' | el, ci, cl, d, o, u | Any vowel |
| lower case 'n' | m, u, x, r, h, s | dn, gn, kn, mn, pn |
| lower case 'd' | cl, j, | b, t |
| lower case 'a' | el, ci, cl, d, o, u | Any vowel |

**Appendix C: FDA Prescription Study Responses**

| Inpatient Medication Order | Outpatient Medication Order | Voice Prescription |
|---|---|---|
| Zaganda | Caranda | Losanda |
| Zazanda | Caranda | Losanda |
| Zazanda | Casanda | Lozanda |
| Zazanda | Casanda | Lozanda |
| Zazanda | Casandra | Lozanda |
| Zazanda | Laranda | Lozanda |
| Zazanda | Lasanda | Lozanda |
| | | Lozanda |
| | | Lozanda |
| | | Lozanda |
| | | Lozanda |
| | | Lozanda |

**Appendix D:** **Names Lacking Orthographic and/or Phonetic Similarity.**

| Name | Similarity to Lazanda |
|---|---|
| Lozol | Look |
| Cozaar | Look |
| Taztia XT | Look |
| Coumadin | Look |
| Lysteda | Look |
| Lovenox | Look |
| Zolinza | Look |
| Zoladex | Look |
| Loperamide | Look |
| Synercid | Look |
| Lysodren | Look |
| Lipitor | Look |
| Capoten | Look |
| Synalar | Look |
| Laryssa | Look and Sound |
| Loryna | Look and Sound |
| Lialda | Look and Sound |
| Lysteda | Look and Sound |

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

| Proprietary Name | Similarity to Lazanda | Status and Date |
|---|---|---|
| Larodopa<br>(Levodopa)<br>Capsules and Tablets | Look | The year of last recorded sales was in (b) (4)[7]. |

**Appendix F: Product used in compounding, not likely to be written on a prescription order**

| Proprietary Name | Similarity to Lazanda | Status and Date |
|---|---|---|
| Lavandin Oil Abrial | Look | This product is used in pharmaceutical compounding and would not be dispensed directly to a patient. |

**Appendix G: Veterinarian drug product**

| Proprietary Name | Similarity to Lazanda | Status and Date |
|---|---|---|
| Leventa<br>(Levothyroxine Sodium)<br>Oral Solution | Look | Leventa is indicated for the treatment of canine hypothyroidism. It is dispensed through veterinary clinics so it is unlikely it would get confused with Lazanda. |

[7]Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com, accessed on January 22, 2011.

**Appendix H:** Names never marketed

| Proprietary Name | Similarity to Lazanda | Status and Date |
|---|---|---|
| (b) (4) | | |
| (b) (4) | | |
| (b) (4) | | |
| (b) (4) | | |

**Appendix I: Products with multiple differentiating product characteristics and/or orthographic/phonetic differences**

| Product name with potential for confusion | Similarity to Lazanda | Strength | Signa | Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described<br>(Lazanda vs. Product) |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril; 100 mcg spray in each nostril (200 mcg); 400 mcg spray in one nostril; 400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Caziant (Desogestrel and Ethinyl Estradiol) Tablets | Look | 7 days: 0.1 mg/0.025 mg<br>7 days: 0.125 mg/0.025 mg<br>7 days: 0.15 mg/0.025 mg<br>7 days: Inert | One tablet orally once daily | The cross-stroke of the letter "t" in Caziant may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. tablet<br>**Strength:** 100 mcg or 400 mcg per spray vs. 0.1 mg/0.025 mg, 0.125 mg/0.025 mg, 0.15 mg/0.025 mg<br>Lazanda will be available in two strengths so the strength would have to be specified on a prescription whereas the tablet strengths of Caziant would not be specified. |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Zegerid (Omeprazole and Sodium Bicarbonate) Capsules Powder for oral suspension | Look | Capsules:<br>20 mg/1100 mg<br>40 mg/1100 mg<br>Powder for suspension:<br>20 mg/1680 mg<br>40 mg/1680 mg | 20 mg or 40 mg orally once daily | **Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. capsule or suspension<br>**Strength:** 100 mcg or 400 mcg per spray vs. 20 mg/1100 mg, 40 mg/1100 mg, 20 mg/1680 mg, or 40 mg/1680 mg |
| Zavesca (Miglustat) Capsules | Look | 100 mg | 100 mg (one capsule) orally three times per day<br>Renal dose: 100 mg orally once or twice daily | The potential downstroke letter "z" and the upstroke letter "d" in Lazanda may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily, twice daily, or three times per day<br>**Dosage form:** Nasal spray vs. capsule |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Avandia (Rosiglitazone) Tablets | Look | 2 mg, 4 mg, and 8 mg | 2 mg twice daily;<br>4 mg or 8 mg once daily | The beginning letter "L" and the potential downstroke letter "z" in Lazanda may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily or twice daily<br>**Dosage form:** Nasal spray vs. tablet |

| Product name with potential for confusion | Similarity to Lazanda | Strength | Signa | Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described<br><br>(Lazanda vs. Product) |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Canasa (Mesalamine) Rectal Suppositories | Look | 1 g | 1 g (one suppository) rectally at bedtime | The upstroke letter "d" in Lazanda may help to differentiate the names.<br><br>**Route of administration:** Intranasal vs. rectal<br><br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. at bedtime<br><br>**Strength:** 100 mcg or 400 mcg per spray vs. 1 g<br><br>**Dosage form:** Nasal spray vs. rectal suppository<br><br>Lazanda will be available in two strengths so the strength would have to be specified on a prescription whereas Canasa is available in a single strength so does not have to be specified. |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Namenda<br>(Memantine HCl)<br>Tablets<br>Oral Solution<br><br>Namenda XR<br>(Memantine HCl)<br>Extended-release<br>Tablets | Look | Namenda<br>5 mg and 10 mg<br>Oral solution:<br>2 mg/mL<br><br>Namenda XR<br>7 mg, 14 mg,<br>21 mg, and 28 mg | Namenda<br>10 mg orally twice daily<br>Dosage titration:<br>5 mg once daily. Increase in 5 mg increments to 10 mg/day (5 mg twice a day), 15 mg/day (5 and 10 mg as separate doses), and 20 mg/day (10 mg twice a day). The minimum recommended interval between dose increases is 1 week<br><br>Namenda XR<br>28 mg once daily<br>Dosage titration:<br>7 mg once daily. Increased in 7 mg increments to 28 mg once daily. The minimum recommended interval between dose increases is 1 week | When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily or twice daily<br>**Dosage form:** Nasal spray vs. tablets, extended-release tablets, and oral solution |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Lunesta (Eszopiclone) Tablets | Look | 1 mg, 2 mg, and 3 mg | 1 mg to 3 mg orally at bedtime as needed | The cross stroke in the letter "t" of Lunesta may help to differentiate the names. When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Strength:** 100 mcg/spray and 400 mcg/spray vs. 1 mg, 2 mg, and 3 mg<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily at bedtime as needed<br>**Dosage form:** Nasal spray vs. Tablets |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Lusedra (Fospropofol Disodium) Injection | Look | 1050 mg/30 mL (35 mg/mL) | Initial dose:<br>6.5 mg/kg (455 mg for a 70 kg person) intravenously, not to exceed 577 mg<br>Supplemental doses:<br>1.6 mg/kg intravenously every 4 minutes as needed to achieve desired level of sedation (not to exceed 140 mg per dose) | When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names. Additionally, there are two letters after the upstroke letter "d" in Lusedra whereas there is one in Lazanda.<br>**Strength:** 100 mcg/spray and 400 mcg/spray vs. 1050 mg/30 mL (35 mg/mL)<br>**Route of administration:** Intranasal vs. intravenous<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. every 4 minutes as needed<br>**Dosage form:** Nasal spray vs. injection<br>**Context of use:** Not used during surgical procedures vs. used during surgical procedures |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Lipofen (Fenofibrate) Capsules | Look | 50 mg and 150 mg | 50 mg to 150 mg orally once daily | Lazanda appears longer in length when written. When written with a cross stroke the letter "f" in Lipofen may help to differentiate the names.<br>**Strength:** 100 mcg/spray and 400 mcg/spray vs. 50 mg and 150 mg<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. capsules |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Sufenta (Sufentanyl Citrate) Injection | Look | 250 mcg/5 mL, 100 mcg/2 mL, and 50 mcg/mL | Analgesia<br>Incremental: 10 to 25 mcg intravenously<br>Infusion: up to 1 mcg/kg/h of expected surgical time<br><br>Anesthesia<br>Incremental: 0.5 to 10 mcg/kg intravenously<br>Infusion: ensure the total dose for the procedure does not exceed 30 mcg/kg | The third position letters ("z" vs. "f") do not look similar. The cross-stroke in the sixth position letter "t" in Sufenta vs. the letter "d" in Lazanda may also help to differentiate the names.<br><br>**Route of administration:** Intranasal vs. intravenous<br><br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. as needed<br><br>**Dosage form:** Nasal spray vs. injection<br><br>**Context of use:** Not used during surgical procedures vs. used during surgical procedures |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril; 100 mcg spray in each nostril (200 mcg); 400 mcg spray in one nostril; 400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Zazole (Terconazole) Vaginal Cream Vaginal Suppositories | Look | Cream: 0.4% and 0.8%<br>Suppositories: 80 mg | Cream 0.4%: 1 applicatorful intravaginally at bedtime for 7 days<br>Cream 0.8%: 1 applicatorful intravaginally at bedtime for 3 days<br>Suppositories: One suppository intravaginally at bedtime for 3 days | Lazanda appears longer in length when written.<br>**Route of administration:** Intranasal vs. intravaginal<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. every day at bedtime'<br>**Strength:** 100 mcg/spray and 400 mcg/spray vs. 0.4%, 0.8%, or 80 mg<br>**Dosage form:** Nasal spray vs. vaginal suppository |
| Fazaclo (Clozapine) Oral Disintegrating Tablet | Look | 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg | Titrate dose starting with 12.5 mg orally once daily or twice daily and gradually increase to 600 mg to 900 mg per day in divided doses (twice daily or three times per day) | The ending letters "nda" vs. "clo" look different when written.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily, twice daily, or three times per day<br>**Dosage form:** Nasal spray vs. tablets |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Losartan (branded name: Cozaar) Tablets | Look | 25 mg, 50 mg, and 100 mg | 25 mg to 100 mg orally once daily | When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. tablets |
| Lucentis (Ranibizumab) Injection | Look | 2 mg/0.2 mL | 0.5 mg intravitreally once per month | When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names. The cross-stroke letter "t" in Lucentis may further help to differentiate the names.<br>**Route of administration:** Intranasal vs. intravitreal<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once per month<br>**Dosage form:** Nasal spray vs. injection<br>**Context of use:** Not used during ophthalmic surgical procedure vs. used during ophthalmic surgical procedure |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Latuda (Lurasidone HCl) Tablets | Look and Sound | 40 mg and 80 mg | 40 mg to 80 mg orally once daily | Lazanda appears longer in length when written. Lazanda contains one upstroke letter ("d") vs. two upstroke letters ("t" and "d") in Latuda. The middle syllables ("-zan-" vs. "-tu-") do not sound similar.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. tablets |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Treanda (Bendamustine HCl) for Injection | Look and Sound | 20 mg and 100 mg | 100 mg/$m^2$ (173 mg for a BSA of 1.73 $m^2$) on days 1 and 2 of a 28-day cycle or 120 mg/$m^2$ (207 mg for a BSA of 1.73 $m^2$) on days 1 and 2 of a 21-day cycle, depending on the indication of use | When written with a downstroke, the letter "z" in Lazanda may help to differentiate the names. The beginning syllables do not sound similar ("La-" vs. "Tre-")<br>**Route of administration:** Intranasal vs. intravenous<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. days 1 and 2 of a 28-day cycle or days 1 and 2 of a 21-day cycle<br>**Dosage form:** Nasal spray vs. for injection |

| Product name with potential for confusion | Similarity to Lazanda | Strength | Signa | Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described<br>(Lazanda vs. Product) |
|---|---|---|---|---|
| Lazanda | N/A | 100 mcg per spray and 400 mcg per spray | 100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours | N/A |
| [redacted] | [redacted] | [redacted] | [redacted] | [redacted] (b) (4) |

| **Product name with potential for confusion** | **Similarity to Lazanda** | **Strength** | **Signa** | **Name confusion is prevented by the combination of stated product characteristics, orthographic and/or phonetic differences as described**<br>**(Lazanda vs. Product)** |
|---|---|---|---|---|
| **Lazanda** | **N/A** | **100 mcg per spray and 400 mcg per spray** | **100 mcg spray in one nostril;<br>100 mcg spray in each nostril (200 mcg);<br>400 mcg spray in one nostril;<br>400 mcg spray in each nostril (800 mcg) every 2 hours as needed for pain, maximum of 4 doses per 24 hours** | **N/A** |
| Lovaza (Omega-3-acid Ethyl Esters) Capsules | Look and Sound | 1 g | 2 g orally twice daily or 4 g once daily | The upstroke of the letter "d" in Lazanda may help to differentiate the names. The middle syllables ("-zan-" vs. "-va-") do not sound similar. The ending syllables sound different due to the "d" vs. "z" sound.<br>**Route of administration:** Intranasal vs. oral<br>**Frequency of administration:** Every 2 hours as needed, up to 4 doses per day vs. once daily<br>**Dosage form:** Nasal spray vs. capsules |

**Appendix J:** **Risk of medication errors due to product confusion minimized by the reasons described**

| **Proprietary Name:**<br>**Lazanda (Fentanyl) Nasal Spray** | **Strength:**<br>**100 mcg and 200 mcg per spray** | **Signa:**<br>**100 mcg spray in one nostril; 100 mcg spray in each nostril (200 mcg); 400 mcg spray in one nostril; 400 mcg spray in each nostril (800 mcg)** |
|---|---|---|
| **Failure Mode:**<br>**Name confusion** | **Causes**<br>**(could be multiple)** | **Rationale** |
| [redacted] | [redacted] | [redacted] (b) (4) |

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/s/

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