CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202278Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	November 6, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Zecuity (Sumatriptan) Iontophoretic Transdermal Patch 6.5 mg over 4 hours
Application Type/Number:	NDA 202278
Applicant/Sponsor:	NuPathe
OSE RCM #:	2012-1957

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

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Zecuity, 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 REGULATORY HISTORY

This is a 505(b)(2) application. The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the proposed proprietary name, Zelrix[***], for this product and found it unacceptable in OSE Review # 2010-2663 dated March 9, 2011. The Applicant was notified via letter on March 9, 2011. Subsequently, the Applicant submitted the proposed proprietary name, Zecuity, for review on June 1, 2011. This submission included an assessment of the proposed proprietary name completed by an external vendor, Addison Whitney, which identified no similar names to Zecuity. DMEPA evaluated the proposed proprietary name, Zecuity, for this product and found it acceptable in OSE Review # 2011-2178 dated August 22, 2011. The Applicant was notified via letter on August 24, 2011. The Division of Neurology Products (DNP) issued a Complete Response (CR) letter for this application secondary to CMC and device deficiencies among others on August 29, 2011. The Applicant resubmitted the application on July 16, 2012 and requested a review of the proposed proprietary name, Zecuity, on August 17, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 17, 2012 proprietary name submission. None of the proposed product characteristics for Zecuity have changed since our previous review of the name.

- Active Ingredient: Sumatriptan
- Indication of Use: Acute treatment of migraine attacks, with or without aura, in adults
- Route of Administration: Transdermal (Topical)
- Dosage Form: Iontophoretic Transdermal System
- Strength: 6.5 mg over 4 hours
- Dose and Frequency: Apply one patch; maximum recommended dose is two patches in 24 hours
- How Supplied: Cartons of 6 patches
- Storage: Room temperature

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

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. The Division of Neurology Products (DNP) expressed concerns that the proposed name, Zecuity, is similar to "security" which may imply that the product is very safe. OPDP re-evaluated the name taking into consideration DNP's comment, but maintained the position that Zecuity is acceptable from a promotional perspective. DMEPA and DNP 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 September 24, 2012 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 did not indicate in their submission that the proposed name, Zecuity, is derived from any particular source. 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.

2.2.4 FDA Name Simulation Studies

One hundred and four practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with, appear, or sound similar to any currently marketed products. The verbal prescription study shows that the letters 'Z' and 'S' are phonetically similar. The written prescription studies show that the misinterpretations were primarily in the infix 'cui.' See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, August 30, 2012 e-mail, the Division of Neurology Products provided a promotional concern at the initial phase of the proprietary name review, which is noted in Section 2.1.

2.2.6 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, Zecuity. Table 1 lists the names with orthographic or spelling similarity to the proposed proprietary name, Zecuity, identified

by the primary reviewer (PR) and the Expert Panel Discussion (EPD), which were not initially identified and evaluated in OSE Review # 2011-2178.

Table 1: Collective List of Potentially Similar Names (PR and EPD)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Lacrisert	EPD	Zervalx	EPD	Milantex	PR
Zeasorb	EPD	Gravity	PR	Zolvit	EPD
Curity	PR	Calvite P&D	EPD	Clarity Essential Oil	PR
Zometa	EPD	Carnitor	EPD	Clarity EFR	PR
Clinistix	PR	Fruity C	EPD	Clarity Compound	PR
Celontin	EPD	Cernitin Af	PR	Lucentis	EPD
Zarontin	EPD	Claritin	EPD	Folvite	PR
Zilactin	EPD	Triatex	PR	(b) (4)	EPD
Nicalex	PR	Erivedge	EPD	Velivet	EPD
Zincate	EPD	Focalin	EPD	Serenity	PR
Clearly Confident Antifungal	PR	Ferndex	PR	Micardis	EPD
Clearly Confident Triple Action	PR	Zileuton	EPD	(b) (4)	EPD
Crantex	EPD	[redacted]	[redacted]	[redacted]	[redacted]

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Our analysis of the thirty-seven names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined thirty-seven names will not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Neurology Products via e-mail on October 5, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products on October 9, 2012, they stated no additional concerns with the proposed proprietary name, Zecuity.

2 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068.

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Zecuity, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your August 17, 2012 submission are altered, the name must be resubmitted for review.

3 REFERENCES

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

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

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

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

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

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

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

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

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

17. ***Walgreens (www.walgreens.com)***

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

18. ***Rx List (www.rxlist.com)***

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

19. ***Dogpile (www.dogpile.com)***

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

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

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

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

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

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies 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).

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] 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

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

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

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

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

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

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

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

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

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

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

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

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

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

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

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

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

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

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

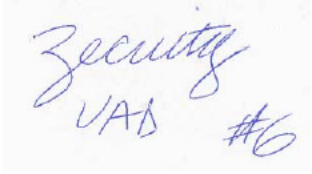
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Zecuity	Scripted May Appear as	Spoken May Be Interpreted as
Upper case 'Z'	C, F, L, M, S, T, V, Y	C, S, X
Lower case 'z'	c, e, g, n, m, q, r, s, v, y	c, s, x
Lower case 'e'	a, c, i, l	any vowel
Lower case 'c'	a, e, i, l	ck, k
Lower case 'u'	n, y, v, w, a, ie, ei, rr, o	any vowel
Lower case 'i'	e, c, l, r	any vowel
Lower case 't'	f, x, l	d
Lower case 'y'	f, g, ej, ij, j, p, u, v, x, z	any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Study (Conducted on September 4, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Zecuity Apply 1 patch at onset of migraine	Zecuity Use as directed # 6
Outpatient Prescription: 	

192 People Received Study

104 People Responded

Study Name: Zecuity

Total	36	31	37	
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
CUDE	0	1	0	1
SECUITY	0	3	0	3
SECUTI	0	1	0	1
SEQUDI	0	1	0	1
SIQUIDY	0	1	0	1
SOQUIDI	0	1	0	1
XACUITY	0	1	0	1
ZACINTY	1	0	0	1
ZACUDE	0	1	0	1
ZACUDI	0	1	0	1
ZACUDY	0	1	0	1
ZACUETY	0	1	0	1
ZACUITY	0	5	0	5
ZECINITY	1	0	0	1
ZECINITY PATCH	1	0	0	1
ZECIRETY	2	0	0	2
ZECIUETY	1	0	0	1
ZECRUITY	0	0	1	1
ZECUDI	0	1	0	1
ZECUITY	19	4	31	54
ZECUITY PATCH	1	0	0	1

ZECURITY	5	1	4	10
ZECURITZ	0	0	1	1
ZEINITY	1	0	0	1
ZEIUITY	1	0	0	1
ZEQUIETI	0	1	0	1
ZEQUITY	0	1	0	1
ZERINITY	1	0	0	1
ZEVITY	1	0	0	1
ZEVUNITY	1	0	0	1
ZICUITY	0	1	0	1
ZIKUTI	0	1	0	1
ZUCUITY	0	1	0	1
ZUCUTI	0	1	0	1
ZUQUIDE	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 Zecuity	Failure preventions
1.	Lacrisert	Hydroxypropyl Cellulose	Look alike	The pair has sufficient orthographic differences.
2.	Zeasorb	Miconazole	Look alike	The pair has sufficient orthographic differences.
3.	Zincate	Zinc Salts	Look alike	The pair has sufficient orthographic differences.
4.	Zometa	Zoledronic Acid	Look alike	The pair has sufficient orthographic differences.
5.	Clinistix		Look alike	The pair has sufficient orthographic differences
6.	Celontin	Methsuximide	Look alike	The pair has sufficient orthographic differences
7.	Zarontin	Ethosuximide	Look alike	The pair has sufficient orthographic differences
8.	Zilactin	Benzocaine	Look alike	The pair has sufficient orthographic differences
9.	Zileuton		Look alike	The pair has sufficient orthographic differences
10.	Gravity		Look alike	Product is not a drug, but an enteral feeding set.
11.	Clearly Confident Antifungal	Miconazole	Look alike	Name identified in Natural Medicine and Natural Standard databases. Unable to find product characteristics in commonly used drug databases.
12.	Clearly Confident Triple Action	Clotrimazole	Look alike	Name identified in Natural Medicine and Natural Standard databases. Unable to find product characteristics in commonly used drug databases.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Zervalx (Levomefolate) Tablets <u>Strength:</u> 1 mg <u>Dosage:</u> One tablet by mouth once daily	<u>Orthographic:</u> Both names begin with 'Ze,' contain a cross stroke letter 't' at the sixth position, and have seven letters. The letter 'r' in Zervalx and the letter 'c' in Zecuity look similar when scripted. The letter 'v' in Zervalx and the letter 'u' in Zecuity look similar when scripted. The letter 'x' in Zervalx and the letter 'y' in Zecuity look similar when scripted. <u>Strength:</u> Both products are available in one strength, which may be omitted from a prescription.	<u>Dosage and Administration:</u> Zervalx will be prescribed as 'Take one tablet' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' <u>Frequency of administration:</u> Zervalx is administered once daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b)(4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2.	Lucentis (Ranibizumab) Injection Strength: 0.3 mg per 0.05 mL, 0.5 mg per 0.05 mL Dosage: 0.3 mg or 0.5 mg via intravitreal injection once a month	Orthographic: The first letter 'L' and 'Z' look similar when scripted. Both names contain the letter 'c' at the third position and the cross stroke letter 't' at the sixth position. The letter pair 'en' in Lucentis and the letter pair 'ui' in Zecuity look similar when scripted. Frequency of administration: Both products may be prescribed as a one time dose.	Orthographic: Lucentis does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: Since Lucentis is available in two strengths, a strength would need to be specified on a prescription. Since Zecuity is available in one strength, the strength may be omitted from a prescription. The strengths of Lucentis and Zecuity do not overlap. Although, the 6.5 mg dose of Zecuity can be achieved with the 0.5 mg per 0.05 mL strength of Lucentis, a dosage of Lucentis 6.5 mg exceeds the recommended maximum dosage of Lucentis.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Calvite P&D (Calcium, Phosphorus, and Vitamin D) Tablets Strength: Calcium 105 mg, Phosphorus 81 mg, and Vitamin D 120 International Units Dosage: One tablet by mouth three times daily with meals or as directed	Orthographic: The first letter 'C' and 'Z' look similar when scripted. The letter 'a' in Calvite and the letter 'e' in Zecuity look similar when scripted. The letter 'l' in Calvite and the letter 'c' in Zecuity look similar when scripted. The letter 'v' in Calvite and the letter 'u' in Zecuity look similar when scripted. Both names contain the letter pair 'it' starting at the fifth position. The root name Calvite and Zecuity have seven letters. Dosage: Both products can be prescribed as 'Use as directed.' Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: Calvite contains an upstroke letter 'l' at the third position vs. Zecuity does not contain an upstroke letter at the third position. Calvite does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
4.	Carnitor (Levocarnitine) Solution, Injection, and Tablets Strength: 1 g per 10 mL Solution, 200 mg per mL Injection, 330 mg Tablets Dosage: Solution: 1 g by mouth once to three times daily with food; 50 mg/kg/day to 100 mg/kg/day by mouth in divided doses in pediatrics; Injection: 50 mg/kg intravenous bolus injection or intravenous infusion; 10 mg/kg to 20 mg/kg bolus injection into venous return line after each dialysis session; Tablets: 990 mg by mouth two to three times daily with food; 50 mg/kg/day to 100 mg/kg/day in divided doses in pediatrics	Orthographic: The first letter 'C' and 'Z' look similar when scripted. The letter 'a' in Carnitor and the letter 'e' in Zecuity look similar when scripted. The letter 'r' at the third position in Carnitor and the letter 'c' in Zecuity look similar when scripted. The letter 'n' in Carnitor and the letter 'u' in Zecuity look similar when scripted. Both names contain the letter pair 'it' starting at the fifth position. Frequency of administration: Since Carnitor may be administered after a dialysis session, both products may be prescribed as a one time dose.	Orthographic: Carnitor does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: The strengths and dosage of Carnitor do not overlap and are not achievable with the strength of Zecuity. Route of administration: Carnitor is administered orally or intravenously, which would need to be specified on a prescription. The routes of administration for Carnitor do not overlap with the topical route of administration for Zecuity.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5.	Zolvit (Hydrocodone and Acetaminophen) Solution Strength: Hydrocodone 10 mg and Acetaminophen 300 mg per 15 mL Dosage: 2.8 mL to 11.25 mL by mouth every four to six hours as needed for pain	Orthographic: Both names begin with 'Z' and contain the letter pair 'it' starting at the fifth position. The letter 'l' in Zolvit and the letter 'c' in Zecuity look similar when scripted. The letter 'v' in Zolvit and the letter 'u' in Zecuity look similar when scripted. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: Zolvit contains an upstroke letter at the third position vs. Zecuity does not contain an upstroke letter at the third position. Zolvit does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position. Dosage and Administration: Zolvit will be prescribed as 'Take XX mL' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Zolvit is administered every four to six hours as needed for pain vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Velivet (Desogestrel and Ethinyl Estradiol) Tablets Strength: Desogestrel 0.125 mg and Ethinyl Estradiol 0.025 mg, then Desogestrel 0.15 mg and Ethinyl Estradiol 0.025 mg, and then Desogestrel 0.1 mg and Ethinyl Estradiol 0.025 mg for one week Dosage: One tablet by mouth once daily	Orthographic: The first letter 'V' and 'Z' look similar when scripted. Both names contain the letter 'e' at the second position. The letter 'l' in Velivet and the letter 'c' in Zecuity look similar when scripted. The letter 'v' at the fifth position in Velivet and the letter 'u' in Zecuity look similar when scripted. The letter 'e' at the sixth position in Velivet and the letter 'i' in Zecuity look similar when scripted. Both names contain the cross stroke letter 't' in the suffix. Strength: Both products are available in one strength, which may be omitted from a prescription. Dosage: Both products can be prescribed as 'Use as directed.'	Orthographic: Velivet contains an upstroke letter at the third position vs. Zecuity does not contain an upstroke letter at the third position. Velivet does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Claritin (Loratadine) Tablets, Capsules, and Syrup Strength: 10 mg Tablets and Capsules; 5 mg per 5 mL Syrup Dosage: 5 mg to 10 mg by mouth once daily	Orthographic: The first letter 'C' and 'Z' look similar when scripted. The letter 'l' in Claritin and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Claritin and the letter 'c' in Zecuity look similar when scripted. Both names contain the letter pair 'it' starting at the fifth position.	Orthographic: Claritin does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: The strengths and dosage of Claritin do not overlap and are not achievable with the strength of Zecuity. Dosage form: Claritin is available in multiple dosage forms, which would need to be specified on a prescription. The dosage forms of Claritin do not overlap with the transdermal system dosage form of Zecuity.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8.	Crantex (Guaifenesin and Phenylephrine) Liquid Strength: Guaifenesin 100 mg and Phenylephrine 7.5 mg per 5 mL Dosage: 2.5 mL to 10 mL every four to six hours as needed	Orthographic: The first letter 'C' and 'Z' look similar when scripted. The letter 'r' in Crantex and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Crantex and the letter 'c' in Zecuity look similar when scripted. The letter 'n' in Crantex and the letter 'u' in Zecuity look similar when scripted. Both names contain a cross stroke letter 't' in the suffix. The letter 'x' in Crantex and the letter 'y' in Zecuity look similar when scripted. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: The suffix 'tex' in Crantex and the suffix 'ty' in Zecuity look different when scripted. Dosage and Administration: Crantex will be prescribed as 'Take XX mL' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed' Frequency of administration: Crantex is administered every four to six hours as needed vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
9.	Erivedge (Vismodegib) Capsules Strength: 150 mg Dosage: One capsule by mouth once daily	Orthographic: The first letter 'e' and 'z' look similar when scripted. The letter 'r' in Erivedge and the letter 'e' in Zecuity look similar when scripted. The letter 'i' in Erivedge and the letter 'c' in Zecuity look similar when scripted. The letter 'v' in Erivedge and the letter 'u' in Zecuity look similar when scripted. Both names contain an upstroke letter at the sixth position that is immediately followed by a down stroke letter. Strength: Both products are available in one strength, which may be omitted from a prescription.	Dosage: Erivedge will be prescribed as 'Take one capsule' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed' Frequency of administration: Erivedge is administered once daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
10.	Focalin (Dexmethylphenidate) Tablets Strength: 2.5 mg, 5 mg, 10 mg Dosage: One tablet by mouth twice daily	Orthographic: The first letter 'f' and 'z' look similar when scripted. Both names contain the letter 'c' at the third position. The letter 'a' in Focalin and the letter 'u' in Zecuity look similar when scripted. Both names contain an upstroke letter in the suffix.	Orthographic: Focalin does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: Since Focalin is available in three strengths, a strength would need to be specified on a prescription. Since Zecuity is available in one strength, the strength may be omitted from a prescription. The strengths of Focalin and Zecuity do not overlap. Frequency of administration: Focalin is administered twice daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
11.	Fruity C (Ascorbic Acid) Tablets Strength: 250 mg Dosage: One tablet by mouth one to two times daily	Orthographic: The first letter 'f' and 'z' look similar when scripted. The letter 'r' in Fruity and the letter 'e' in Zecuity look similar when scripted. Both names contain the letter string 'uity.' Strength: Both products are available in one strength, which may be omitted from a prescription.	Dosage: Fruity C will be prescribed as 'Take one tablet' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed' Frequency of administration: Fruity C is administered one to two times daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
12.	Micardis (Telmisartan) Tablets Strength: 20 mg, 40 mg, 80 mg Dosage: One tablet by mouth once daily	Orthographic: The first letter 'M' and 'Z' look similar when scripted. The letter 'i' at the second position in Micardis and the letter 'e' in Zecuity look similar when scripted. Both names contain the letter 'c' at the third position. The letter 'a' in Micardis and the letter 'u' in Zecuity look similar when scripted. The letter 'r' in Micardis and the letter 'i' in Zecuity look similar when scripted. Both names contain an upstroke letter at the sixth position.	Orthographic: Micardis does not contain any down stroke letter vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: Since Micardis is available in three strengths, a strength would need to be specified on a prescription. Since Zecuity is available in one strength, the strength may be omitted from a prescription. The strengths of Micardis and Zecuity do not overlap. Frequency of administration: Micardis is administered once daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b)(4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	Milantex (Aluminum Hydroxide, Magnesium Hydroxide, and Simethicone) Suspension Strength: Aluminum Hydroxide 200 mg, Magnesium Hydroxide 200 mg and Simethicone 20 mg per 5 mL Dosage: 5 mL to 20 mL by mouth between meals, at bedtime, or as directed	Orthographic: The first letter 'M' and 'Z' look similar when scripted. The letter 'i' in Milantex and the letter 'e' in Zecuity look similar when scripted. The letter 'l' in Milantex and the letter 'c' in Zecuity look similar when scripted. The letter 'a' in Milantex and the letter 'u' in Zecuity look similar when scripted. Both names contain a cross stroke letter 't' at the sixth position. The letter 'x' in Milantex and the letter 'y' in Zecuity look similar when scripted. Strength: Both products are available in one strength, which may be omitted from a prescription. Dosage: Both products can be prescribed as 'Use as directed.'	Orthographic: Milantex contains an upstroke letter at the third position vs. Zecuity does not contain an upstroke letter at the third position. The letter string 'ntex' in Milantex and the letter string 'ity' in Zecuity look different when scripted.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b)(4)mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
14.	Cernitin Af (Cernitin Extract, Phytosterol and Saw Palmetto Complex, and Vitamin E) Tablets Strength: Cernitin Extract 189 mg, Phytosterol and Saw Palmetto Complex 143 mg, and Vitamin E 50 International Units Dosage: Two tablets by mouth daily with meals	Orthographic: The first letter 'c' and 'z' look similar when scripted. Both names contain the letter 'e' at the second position. The letter 'r' in Cernitin and the letter 'c' in Zecuity look similar when scripted. The letter 'n' at the fourth position in Cernitin and the letter 'u' in Zecuity look similar when scripted. Both names contain the letter pair 'it' starting at the fifth position. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: Cernitin does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. If written, the modifier 'Af' would differentiate Cernitin from Zecuity Dosage and Administration: Cernitin will be prescribed as 'Take two tablets' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Cernitin is administered once daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
15.	Clarity Essential Oil (Basil, Cardamom, Rosemary, Peppermint, Rosewood, Geranium, Lemon, Palmarosa, Ylang Ylang, Bergamot, Roman Chamomile, and Jasmine) Dosage: Apply on temples, wrists, and neck	Orthographic: The first letter 'c' and 'z' look similar when scripted. The letter 'l' in Clarity and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Clarity and the letter 'c' in Zecuity look similar when scripted. Both names contain the letter string 'ity' in the suffix. Strength: Both products are available in one strength, which may be omitted from a prescription. Dosage: Both products can be prescribed as 'Use as directed.'	Orthographic: Clarity contains an upstroke letter at the second position vs. Zecuity does not contain an upstroke letter at the second position. There are several products with the root name Clarity. A prescription for Clarity would need the modifier 'Essential Oil,' 'EFR,' or 'Compound,' which would differentiate it from Zecuity.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b)(4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
16.	Clarity EFR (Dill, Olive, Self-Heal, Shasta Daisy, Scleranthus, Tansy, Sage, Chamomile Flowers, Distilled Water, Vegetable Glycerin) Dosage: Three to five drops under the tongue every 5 to 10 minutes until symptoms subside and relief occurs	Orthographic: The first letter 'c' and 'z' look similar when scripted. The letter 'l' in Clarity and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Clarity and the letter 'c' in Zecuity look similar when scripted. Both names contain the letter string 'ity' in the suffix. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: Clarity contains an upstroke letter at the second position vs. Zecuity does not contain an upstroke letter at the second position. There are several products with the root name Clarity. A prescription for Clarity would need the modifier 'Essential Oil,' 'EFR,' or 'Compound,' which would differentiate it from Zecuity. Dosage: Clarity EFR will be prescribed as 'Take three to five drops' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Clarity EFR is administered every 5 to 10 minutes until symptoms subside and relief occurs vs. Zecuity is administered at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
17.	Clarity Compound (Bacopa Herb, Ginkgo Leaf, Gotu Kola Herb, Lemon Balm herb, Schisandra Berry, and Rosemary Herb) Dosage: Two mL to four mL by mouth three times daily as needed	Orthographic: The first letter 'c' and 'z' look similar when scripted. The letter 'l' in Clarity and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Clarity and the letter 'c' in Zecuity look similar when scripted. Both names contain the letter string 'ity' in the suffix. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: Clarity contains an upstroke letter at the second position vs. Zecuity does not contain an upstroke letter at the second position. There are several products with the root name Clarity. A prescription for Clarity would need the modifier 'Essential Oil,' 'EFR,' or 'Compound,' which would differentiate it from Zecuity. Dosage: Clarity Compound will be prescribed as 'Take two mL to four mL' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Clarity Compound is administered three times daily as needed vs. Zecuity is administered at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
18.	Ferndex (Dextroamphetamine) Tablets Strength: 5 mg Dosage: One-half to one tablet by mouth once or twice daily	Orthographic: The first letter 'f' and 'z' look similar when scripted. Both names contain the letter 'e' at the second position. The letter 'r' in Ferndex and the letter 'c' in Zecuity look similar when scripted. The letter 'n' in Ferndex and the letter 'u' in Zecuity look similar when scripted. Both names contain an upstroke letter in the suffix. The letter 'x' in Ferndex and the letter 'y' in Zecuity look similar when scripted. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: The letter string 'dex' in Ferndex and the letter pair 'ty' in Zecuity look different when scripted. Dosage and Administration: Ferndex will be prescribed as 'Take one-half to one tablet' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Ferndex is administered once or twice daily vs. Zecuity is administered at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b)(4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
19.	Folvite (Folic Acid) Tablets and Injection Strength: 0.25 mg, 1 mg Tablets; 5 mg per mL Injection Dosage: 0.25 mg to 15 mg by mouth once daily; 0.4 mg to 1 mg subcutaneously, intravenously, or intramuscularly once daily	Orthographic: The first letter 'f' and 'z' look similar when scripted. The letter 'l' in Folvite and the letter 'c' in Zecuity look similar when scripted. The letter 'v' in Folvite and the letter 'u' in Zecuity look similar when scripted. Both names contain the letter pair 'it' starting at the fifth position.	Orthographic: Folvite contains an upstroke letter at the third position vs. Zecuity does not contain an upstroke letter at the third position. Folvite does not contain any down stroke letters vs. Zecuity contains a down stroke letter at the seventh position, giving the two names a different shape when scripted. Strength: Folvite is available in multiple strengths, which would need to be specified on a prescription. Zecuity is available in one strength, which may be omitted from a prescription. The strengths of Folvite do not overlap with the strength of Zecuity. Route of administration: Folvite can be administered orally, subcutaneously, intravenously, or intramuscularly vs. Zecuity is administered topically, which does not overlap with the routes of administration for Folvite.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
20.	(b) (4)		

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

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
21.	Nicalex (Nicotinic Acid) Tablets Strength: 500 mg Dosage: One tablet by mouth daily	Orthographic: The first letter 'n' and 'z' look similar when scripted. The letter 'i' in Nicalex and the letter 'e' in Zecuity look similar when scripted. Both names contain the letter 'c' at the third position. The letter 'a' in Nicalex and the letter 'u' in Zecuity look similar when scripted. Both names contain an upstroke letter in the suffix. The letter 'x' in Nicalex and the letter 'y' in Zecuity look similar when scripted. Strength: Both products are available in one strength, which may be omitted from a prescription.	Orthographic: The suffix 'lex' in Nicalex and the suffix 'ty' in Zecuity look different when scripted. Dosage: Nicalex will be prescribed as 'Take one tablet' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Nicalex is administered daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
22.	Serenity (Burdock Root, Beth Root, Black Cohosh, Oregon Grape Root, Milkweed) Capsules Dosage: Two capsules by mouth twice daily between meals	Orthographic: The first letter 's' and 'z' look similar when scripted. Both names contain the letter 'e' at the second position. The letter 'r' in Serenity and the letter 'c' in Zecuity look similar when scripted. The letter 'n' in Serenity and the letter 'u' in Zecuity look similar when scripted. Both names contain the letter string 'ity' in the suffix. Strength: Both products are available in one strength, which may be omitted from a prescription.	Dosage: Serenity will be prescribed as 'Take two capsules' vs. Zecuity will be prescribed as 'Apply one patch' or 'Use as directed.' Frequency of administration: Serenity is administered twice daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
23.	Triatex (Triamcinolone) Cream Strength: 0.025%, 0.1%, 0.5% Dosage: Apply to the affected areas two to four times daily	Orthographic: The first letter 't' and 'z' look similar when scripted. The letter 'r' in Triatex and the letter 'e' in Zecuity look similar when scripted. The letter 'a' in Triatex and the letter 'u' in Zecuity look similar when scripted. Both names contain the cross stroke letter 't' in the suffix. The letter 'x' in Triatex and the letter 'y' in Zecuity look similar when scripted.	Orthographic: The suffix 'tex' in Triatex and the suffix 'ty' in Zecuity look different when scripted. Strength: Triatex is available in multiple strengths, which would need to be specified on a prescription. Zecuity is available in one strength, which may be omitted from a prescription. There are no overlaps in strengths between these products. Frequency of administration: Triatex is applied two to four times daily vs. Zecuity is applied at the onset of migraine up to two applications in 24 hours

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
24.	(b) (4)		(b) (4)

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Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Zecuity **Dosage Form:** Iontophoretic Transdermal System **Strength:** (b) (4) mg delivering 6.5 mg over 4 hours **Dosage:** Apply one patch at onset of migraine	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
25.	Curity	Orthographic: The first letter 'C' and 'Z' look similar when scripted. The letter 'r' in Curity and the letter 'c' in Zecuity look similar when scripted. Both names contain the letter string 'ity' in the suffix.	Orthographic: The letter string 'ur' in Curity is shorter when scripted than the letter string 'ecu' in Zecuity. Curity is a family tradename for an OTC product line. Multiple products are available in the product line, such as Curity Alcohol Prep, Curity Baby Oil, and Curity Sterile Saline Solution. Therefore, if a prescription were written for one of these products, it would have to state which Curity product should be dispensed. This will help differentiate the names Zecuity and Curity.

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

/s/

JULIE V NESHIEWAT
11/06/2012

IRENE Z CHAN
11/07/2012

CAROL A HOLQUIST
11/07/2012

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

Date:	March 9, 2011
Application Type/Number:	NDA 202278
Through:	Melina Griffis RPh, Team Leader Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
From:	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Zelrix (Sumatriptan) Iontophoretic Transdermal System, 6.5 mg over 4 hours.
Applicant/sponsor:	NuPathe, Inc
OSE RCM #:	2010-2663

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CONTENTS

EXECUTIVE SUMMARY

This review summarizes the Division of Medication Error Prevention and Analysis' evaluation of the proposed proprietary name, Zelrix, (Sumatriptan) Iontophoretic Transdermal System for NDA 202278. Our evaluation finds the proposed name, Zelrix, vulnerable to confusion with Lidex, Salvax, and Tobrex which would result in medication error because of orthographic similarity and overlapping product characteristics. Thus, we object to the use of the proposed proprietary name, Zelrix, for this product. The Applicant will be notified of these findings via letter.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from NuPathe, Inc. on December 17, 2010, for an assessment of the proposed proprietary name, Zelrix, for NDA 202278 regarding potential name confusion with other proprietary or established drug names in the usual practice settings.

1.2 PRODUCT INFORMATION

Zelrix contains Sumatriptan delivered from an iontophoretic transdermal system. This system uses a low electrical current to move ionized Sumatriptan across the skin to the underlying tissue and blood vessels. Zelrix is presented as 6.5 mg over 4 hours and is indicated for the treatment of migraines, with or without aura. The system is applied topically to the upper arm or upper leg at the onset of a migraine headache and must be activated by the patient to deliver Sumatriptan over four hours. If the patient receives no relief after two hours an additional system may be applied and activated, but no more than two systems should be used in 24 hours. The systems will be packaged in cartons containing (b) (4) 6 which are stored at room temperature.

2 METHODS AND MATERIALS

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

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'Z' 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]

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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)

To identify drug names that may look similar to Zelrix, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (two, capital letter Z and lower case l), down strokes (one, letter Z when scripted), cross strokes (one, lower case x), and dotted (one, lower case i). Additionally, several letters in Zelrix may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Zelrix.

When searching to identify potential names that may sound similar to Zelrix, the DMEPA staff search for names with similar number of syllables (two), stresses (ZEHL-riks or zehl-RIKS), and placement of vowel and consonant sounds. (See Appendix B) The Sponsor's intended pronunciation (ZEL-rix) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 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. (See Appendix C for samples and results.)

3 RESULTS

The names identified from DMEPA's methods as potential sources for name confusion with Zelrix are listed below.

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 57 names as having some similarity to the name Zelrix. (See Table 1 on Page 3.)

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of February 14, 2011.

Table 1. Names identified in database searches presented at CDER Expert Panel

Look-alike names identified (n= 38)				Sound-alike names identified (n=14)		Look-alike and sound- alike names (n=5)
Alrex	Librax	Taclonex	Zetia	Amrix	Zanaflex	Cerebyx
Cedax	Librium	Xelox	Zmax	Celebrex	Zephrex	Cervarix
Celexa	Lidex	Zalban	Zofran	Serax	(b) (4)	Zelrix
(b) (4)	Liotrix	Zebeta	Zoladex	Solurex	(b) (4)	Zetrix
Codrix	Loprox	Zelapar	Zolinza	Sprix	(b) (4)	Zostrix
Didrex	Mentax	Zeldox	Zoloft	(b) (4)	Zolpimist	
Esidrix	Mobic	Zelnorm	Zolvit	Xanax	(b) (4)	
Feridex	(b) (4)	Zerit	Zovirax			
Flarex	Salpix	Zerlor	Zyvox			
(b) (4)	Selsun					

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Table 1) and noted no additional names thought to have orthographic or phonetic similarity to Zelrix.

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 PRESCRIPTION ANALYSIS STUDIES

A total of 30 practitioners responded with none of the responses overlapping with an existing name. Nine of the participants interpreted the name correctly as "Zelrix," with correct interpretation occurring in the inpatient and outpatient studies. The remainder of the written responses misinterpreted the drug name. In the verbal studies, one respondent interpreted the name as 'Serex' which is very similar to the marketed product, Serax, which was previously identified in Section 3.1. The remaining responses were misspelled phonetic variations of the proposed name, Zelrix. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 SAFETY EVALUATOR SEARCHES

Independent searches by the primary Safety Evaluator resulted in six additional names which were thought to look or sound similar to Zelrix and represent a potential source of drug name confusion.

The names identified to have look-alike similarities are Tobrex, Zentrip, and Zotex. The names, Salvax, Valtrex, and (b) (4) * were identified to have look-alike and sound-

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alike similarities. In addition, the identified name, Serax, was noted to also have look-alike similarity to Zelrix. Thus, we identified a total of 63 names: six identified by the primary safety evaluator and 57 identified in section 3.1 above.

3.5 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

3.5.1 Initial Phase of Review

In response to the OSE, January 3, 2011 e-mail, Division of Neurology Products (DNP) did not have any concerns on the proposed name at the initial phase of the name review.

3.5.2 Midpoint of Review

DMEPA notified the Division of Neurology Products via e-mail that we had no concerns with the proposed proprietary name, Zelrix, on February 16, 2011. Per e-mail correspondence from the Division of Neurology Products on February 17, 2011, they stated no additional concerns with the proposed proprietary name, Zelrix.

4 DISCUSSION

This proposed name, Zelrix, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Neurology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated 63 names for their potential similarity to the proposed name, Zelrix. No other aspects of the name were considered to pose potential confusion with the name.

Sixteen of the 63 names were determined to not likely be confused with the proposed name, Zelrix, for the reasons described in Appendix D and thus not evaluated further.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 47 names and lead to medication errors. This analysis determined that the name similarity between Zelrix and 44 of the identified names was unlikely to result in medication error for the reasons presented in Appendices E through F.

Our assessment of the proposed proprietary name, Zelrix, identified that medication errors are likely to occur with the remaining three names, Lidex, Salvax and Tobrex, which are marketed products due to the look-alike and/or sound-alike similarity with the proposed proprietary name and overlapping product characteristics. These similarities are discussed below.

4.2.1 Confusion between Salvax and Zelrix

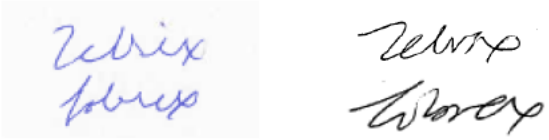
The proposed proprietary name, Zelrix is orthographically and phonetically similar to and shares similar product characteristics with the marketed product, Salvax. The orthographic similarity of this name pair stems from the similar length and shape of the names. This name pair begins with letters that look similar when scripted (Z and S) and share two letters that appear in the same positions (l and x).

The phonetic similarity stems from the fact that both names include two syllables. The first syllable in each name is essentially the same when spoken ("Zel-" vs. "Sal-"). The second syllable includes a vowel followed by the letter 'x' which provides for similar sounding endings ("-ex" vs. "-ax").

In addition to the orthographic and phonetic similarity of this name pair, these products share similar product characteristics which include the following: a numerically similar single strength (**6** % vs. **6.5** mg), and route of administration (topical). The numeric similarity of the strengths may be exacerbated by the use of trailing zeros (e.g. 6.0% vs. 6.5 mg). In addition, since both products are available in a single strength, the omission of the strength during the prescribing and procurements steps of the medication use process is likely. Further, we note that the directions for use of Zelrix and Salvax can be written as "Apply or use as directed" which contributes to the risk of confusion leading to medication error.

4.2.2 Confusion between Tobrex and Zelrix

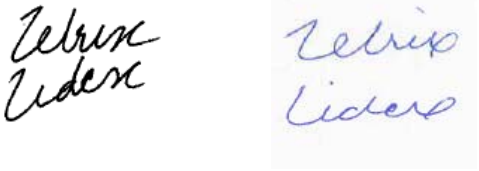
The proposed proprietary name, Zelrix, is orthographically similar to and shares similar product characteristics with the marketed product, Tobrex. The orthographic similarity of these names stem from the similar length, similar appearance of the first letter in each name when scripted (T vs. Z), and nearly similar ending three letters ('-rix' vs. '-rex'). Adding to the visual similarity are the upstrokes (b vs. l) in the middle of each name.



In addition to the orthographic similarity of this name pair, the products share product characteristics such as a single strength which may be omitted in the prescribing and procurements steps of the medication use process, both are topically applied products (ophthalmic ointment vs., transdermal system), and both can be prescribed with directions for use written as "Apply or use as directed" which we believe adds to the risk of confusion leading to medication error.

4.2.3 Confusion between Lidex and Zelrix

The proposed proprietary name, Zelrix, is orthographically similar to and shares similar product characteristics with the once marketed and now discontinued product, Lidex. Although, Lidex is discontinued, drug use data demonstrates healthcare providers continue to use the name, Lidex, in clinical practice when prescribing fluocinonide topical products. In the event a prescription is written for Lidex, although not available, the prescription will be filled with the generic equivalent fluocinonide topical product. Thus, we must consider this name still active. The orthographic similarity of this name pair stems from the similar appearance of the first letters (L vs. Z) and the second letters (i vs. e) when scripted. In addition, both names end with the same two letters '-ex.' Adding to the visual similarity are the upstrokes (d vs. l) in the middle of each name.



In addition to the orthographic similarity of the name pair, these products share similar product characteristics which include the following: single strength availability (which may be omitted in the prescribing and procurements steps of the medication use process), route of administration (topical), and the directions for use (both can be written as "Apply or use as directed"). DMEPA acknowledges Lidex is a proprietary name for discontinued topical products. However, preliminary drug use data demonstrates prescribers continue to use the name, Lidex, in clinical practice and prescribers write "as directed" as the directions for use on these prescriptions.

5 CONCLUSIONS

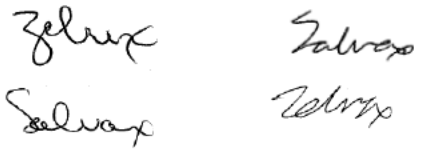
We conclude that the proposed proprietary name Zelrix is vulnerable to name confusion that could lead to medication errors with Salvax due to orthographic and phonetic similarity and shared product characteristics as well as Lidex and Tobrex due to orthographic similarity and overlapping product characteristics. Thus, DMEPA finds the proposed name, Zelrix, unacceptable for this product.

If you have further questions or need clarifications, please contact Laurie Kelley, project manager, at 301-796-5068.

5.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Zelrix, and find it unacceptable for the following reasons.

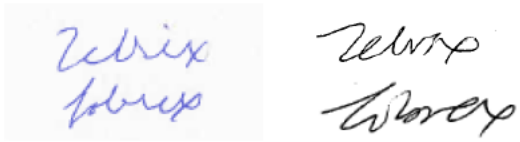
1. The proposed proprietary name, Zelrix is orthographically and phonetically similar to and shares similar product characteristics with the marketed product, Salvax. The orthographic similarity of this name pair stems from the similar length and shape of the names. This name pair begins with letters that look similar when scripted (Z and S) and share two letters that appear in the same positions (l and x).



The phonetic similarity stems from the fact that both names include two syllables. The first syllable in each name is essentially the same when spoken ("Zel-" vs. "Sal-"). The second syllable includes a vowel followed by the letter 'x' which provides for similar sounding endings ("-ex" vs. "-ax").

In addition to the orthographic and phonetic similarity of this name pair, these products share similar product characteristics which include the following: a numerically similar single strength (6 % vs. 6.5 mg), and route of administration (topical). The numeric similarity of the strengths may be exacerbated by the use of trailing zeros (e.g. 6.0% vs. 6.5 mg). In addition, since both products are available in a single strength, the omission of the strength during the prescribing and procurements steps of the medication use process is likely. Further, we note that the directions for use of Zelrix and Salvax can be written as "Apply or use as directed" which contributes to the risk of confusion leading to medication error.

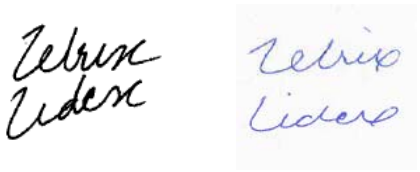
2. The proposed proprietary name, Zelrix, is orthographically similar to and shares similar product characteristics with the marketed product, Tobrex. The orthographic similarity of these names stem from the similar length, similar appearance of the first letter in each name when scripted (T vs. Z), and nearly similar ending three letters ('-rix' vs. '-rex'). Adding to the visual similarity are the upstrokes (b vs. l) in the middle of each name.



In addition to the orthographic similarity of this name pair, the products share product characteristics such as a single strength which may be omitted in the prescribing and procurements steps of the medication use process, both are topically applied products (ophthalmic ointment vs., transdermal system), and both can be prescribed with directions for use written as "Apply or use as directed" which we believe adds to the risk of confusion leading to medication error.

3. The proposed proprietary name, Zelrix, is orthographically similar to and shares similar product characteristics with the once marketed and now discontinued product, Lidex. Although, Lidex is discontinued, drug use data demonstrates healthcare providers continue to use the name, Lidex, in clinical practice when prescribing fluocinonide topical products. In the event a prescription is written for Lidex, although not available, the prescription will be filled with the generic equivalent fluocinonide topical product. Thus, we must consider this name still active. The orthographic

similarity of this name pair stems from the similar appearance of the first letters (L vs. Z) and the second letters (i vs. e) when scripted. In addition, both names end with the same two letters '-ex.' Adding to the visual similarity are the upstrokes (d vs. l) in the middle of each name.



In addition to the orthographic similarity of the name pair, these products share similar product characteristics which include the following: single strength availability (which may be omitted in the prescribing and procurements steps of the medication use process), route of administration (topical), and the directions for use (both can be written as "Apply or use as directed"). DMEPA acknowledges Lidex is a proprietary name for discontinued topical products. However, preliminary drug use data demonstrates prescribers continue to use the name, Lidex, in clinical practice and prescribers write "as directed" as the directions for use on these prescriptions.

We note that you have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, we recommend that you submit a new request for a proposed proprietary name review. (See the Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names,* HTTP://www.fda.gov/cder/guidance/7935dft.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

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6 REFERENCES

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

13. USAN Stems (http://www.ama-assn.org/ama/pub/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.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or

lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

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

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

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

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

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

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

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

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

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 staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the 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.

Table 2. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

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

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/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 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

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

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)].

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 Sponsor 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 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 Sponsor. 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), 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 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 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. . (See Section 4 for limitations of the process).

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 Sponsor 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 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.

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Zelrix	Scripted may appear as	Spoken may be interpreted as
Capital 'Z'	2, C, L, M, T, S, Y	'C,' 'S,' or 'X'
loer case 'z'	c, e, g, n, m, q, r, s, v	'c,' 's,' or 'x'
lower case 'e'	a, c, i, l or o	any vowel
lower case 'l'	b, c, e, or i	'n'
lower case 'r'	n, s, t, or v	'w'
Lower case 'i'	c, e, or l	any vowel
lower case 'x'	a, f, k, n, p, r, t, v or y	'c,' 's,' or 'z'

Appendix C: Prescription study samples and results

Figure 1. Zelrix Study (conducted on January 18, 2011)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order : Zelrix 6.5mg patch. apply and activate at onset of migraine	Zelrix 6.5 mg patch apply and activate at onset of migraine.
Outpatient prescription: Zelrix #4 Use as directed	

FDA Prescription Study Responses.

Study Name: Zelrix

INPATIENT	STRENGTH	VOICE	STRENGTH	OUTPATIENT	STRENGTH
Zeliax	6.5 mg	Serex	5mg	Yelrix	none
Zelimx	6.5 mg	Zarex	6.5mg patc	Zelrix	
Zelinx	6.5 mg	Zelrex	6.5 mg	Zelrix	#4
Zelirex	6.5 mg	Zorax		Zelrix	none
Zeliux	6.5	Zorex	6.5mg	Zelrix	
Zeliux	6.5 mg	Zorix		Zelrix	None given
Zeliux	6.5 mg	Zorix	6.5mg	Zelrix #4	use as dir
Zelivix	6.5mg	thorex	6. 5 mg	zelrix	4
Zelrix	6.5mg	xelrex	6.5 mg	zelrix	
zeliux	6.5 mg	xelrex patch	6.5		
zelivix	6.5 mg Pat				

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

Proprietary Name	Active Ingredient	Similarity to Zelrix	Failure preventions
Codrix	Acetaminophen (500 mg per tablet) with Codeine	Look	Discontinued product with no generic equivalents marketed
(b) (4)		Look	A proposed proprietary name not reviewed by DMEPA and not associated with any pending application.
(b) (4)	(b) (4)	Look	An alternative proposed proprietary name for the approved product, (b) (4)
Salpix	Acetrizoate Sodium	Look	Discontinued product with no generic equivalents
(b) (4)		Look and sound	Not identified as a medication in the searched databases.
Xelox		Look	XELOX is a chemotherapy regimen including Capecitabine and oxaliplatin. The medications would be ordered separately usually (on chemotherapy specific order forms in the inpatient setting).
(b) (4)	(b) (4)	Sound	A proposed proprietary name not review by DMEPA for a product with an inactive IND.
Zalban	Buprenorphine	Look	A product from a foreign market - Japan
Zeldox	Ziprasidone	Look	A product from foreign markets including but not limited to Argentina, Austria, Denmark, New Zealand, and Thailand)
Zelrix	Sumatriptan HCL	Look and sound	Identified only as the product in this application and associated with this Applicant.
Zephrex	Guaifenesin and Pseudoephedrine HCL	Look and sound	Discontinued extended release Guaifenesin product removed from the market by the agency
Zetrix	Cetirizine	Look and sound	A product from a foreign market - Phillipines.
(b) (4)	(b) (4)	Look and sound	A proposed proprietary name not reviewed by DMEPA for a product for which the application has been withdrawn by the Applicant.
(b) (4)	(b) (4)	Look and sound	An alternative proposed name for the product approved as Relistor.
(b) (4)	(b) (4)	Sound	An alternative proposed name for the product approved as (b) (4)
(b) (4)	(b) (4)	Sound	A proposed proprietary name objected to by DMEPA for a product for which the application has been withdrawn by the Applicant.

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

Appendix E: Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Alrex (Loteprednol Etabonate)	Look	0.2% ophthalmic suspension *(single strength)*	One drop into affected eye four times daily.	**Orthographic difference:** The beginning letters in each name appear different (A vs. Z). **Dosage form and route of administration:** Ophthalmic suspension vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Four times daily vs. One time with a single repeat or use as directed. Preliminary drug use data suggests directions are provided by prescribers on prescriptions.
Amrix (Cyclobenzaprine)	Sound	15 mg and 30 mg extended-release capsules	One capsule (15 mg or 30 mg) by mouth once daily	**Phonetic difference:** The first syllable in Amrix lacks a consonant sound. **Strength:** multiple - 15 mg and 30 mg vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Oral capsules vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Cedax (Ceftibuten Dihydrate)	Look	400 mg capsule 90 mg/5 mL and 180 mg/5 mL powder for oral suspension.	Adults: One capsule (400 mg) by mouth daily. Pediatrics: (6 months to 12 years of age): 9 mg/kg (no more than 400 mg) by mouth daily.	**Orthographic difference:** The infix "-ri-" provides greater separation of the upstroke to the 'x' appearing at the end of the name in Zelrix compared to the single letter 'a' in Cedax. **Strength:** Multiple with no numeric overlap (400 mg, 90 mg/5 mL and 180 mg/ 5 mL) vs. single 6.5 mg over 4 hours) **Dosage form and route of administration:** Oral capsule and oral suspension vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Once daily vs. One time with a single repeat or use as directed.
Celebrex (Celecoxib)	Sound	50 mg, 100 mg, 200 mg, and 400 mg capsules	One capsule by mouth once daily or twice daily	**Phonetic difference:** Celebrex includes third syllable and the second syllable which concludes with a 'b' sound. **Strength:** multiple - 50 mg, 100 mg, 200 mg, and 400 mg vs. single - 6.5 mg over 4 hours. **Dosage form and route of administration:** Oral capsules vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** once or twice daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Celexa (Citalapram)	Look	10 mg, 20 mg, and 40 mg tablets and 10 mg/5 mL oral solution	One tablet or two teaspoons (20 mg) by mouth once daily. Dose ranges from 10 to 40 mg (one teaspoon to four teaspoons)	**Orthographic difference:** Celexa includes a letter 'a' appearing after the 'x'. **Strength:** multiple (10 mg, 10 mg/5 mL, 20 mg, and 40 mg) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** Oral tablet and oral solution vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** once daily vs. one time with a single repeat or use as directed.
Cerebyx (Fosphenytoin)	Look and Sound	100 mg PE/2 mL and 500 mg PE/10 mL vials	Loading dose: 15-20 PE mg/kg intravenously *one time*, followed by a maintenance dose of 4-6 PE mg/kg/day intravenously or intramuscularly divided into 2 or more doses.	**Orthographic difference:** Cerebyx includes an extra letter providing additional length when scripted and the letter 'y' providing a down stroke. **Phonetic difference:** Cerebyx includes three syllables and the third begins with a consonant sound "bb" not heard in Zelrix. **Strength:** multiple - 100 mg PE/2 mL and 500 mg PE/10 mL vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Injection for intravenous infusion or intramuscular administration vs. Iontopheretic Transdermal System or patch applied topically.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Cervarix (Papilomavirus vaccine)`	Look and Sound	0.5 mL prefilled syringe *(single strength)*	Inject 0.5 mL (one syringe) intramuscularly one time, then repeat dose in 2 months and in six months from the initial dose.	**Orthographic difference:** Cervarix includes two additional letters providing added length to the name when scripted and lacks any upstrokes. **Phonetic difference:** Cervarix includes three syllables and the consonant sound 'vv' not heard in Zelrix. **Dosage form and route of administration:** injection for intramuscular administration vs. Iontopheretic Transdermal System or patch applied topically.
				(b) (4)

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

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Didrex (Benzphentamine HCl)	Look	50 mg tablet *(single strength)*	One half to one tablet (25 mg to 50 mg) by mouth daily.	**Orthographic difference:** The beginning letters (D vs. Z) appear different when scripted. **Dosage form and route of administration:** Oral tablet vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** once daily vs. One time with a single repeat or use as directed.
Esidrex (Hydrochlorothiazide) (Discontinued product with multiple generic equivalents marketed thus name may be used in clinical practice)	Look	25 mg and 50 mg tablets	One tablet (25 mg or 50 mg) by mouth daily.	**Orthographic difference:** The beginning letters ('Es' vs. 'Z') appear different when scripted. **Strengths:** multiple with no numeric overlap 925 mg and 50 mg) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** once daily vs. One time with a single repeat or use as directed.
Feridex (Ferumoxides)	Look	11.2 mg/mL vial *(single strength)*	Infuse 0.05 mL/kg intravenously over 30 mg prior to MRI of the liver.	**Orthographic difference:** A three letter infix '-eri-' separates the beginning letter from the second upstroke in Feridex compared to a single letter 'e' in Zelrix. **Dosage form and route of administration:** Injection diluted and infused intravenously vs. Iontopheretic Transdermal System or patch applied topically. Feridex use is limited to Radiology as an imaging agent.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Flarex (Fluorometholone Acetate)	Look	0.1% ophthalmic suspension *(single strength)*	One to two drops to affected eyes four times daily.	**Orthographic difference:** The upstroke provided by the 'l' appears adjacent to the beginning letter 'F' in Flarex. **Dosage form and route of administration:** Ophthalmic suspension vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Four times daily vs. One time with a single repeat or use as directed.
Librium (Chlordiazepoxide HCl)	Look	5 mg, 10 mg, and 25 mg capsules	One capsules (5 mg- 25 mg) by mouth three or four times daily.	**Orthographic difference:** Librium includes an extra letter 'm' which provides added length to the appearance. **Strength:** Multiple (5 mg, 10 mg and 25 mg) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** oral capsule vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** three or four times daily vs. One time with a single repeat or use as directed.
Liotrix (the established name for Thyrolar)	Look	Tablets- 1/4, 1/2, 1, 2, and 3 No units list with the strength of this product which contains two active moiety	One tablet (any strength) by mouth daily.	**Orthographic difference:** The letter 'o' provides greater separation of the beginning letter from the second upstroke in Liotrix. In addition, The letter 't' provides a cross stroke in the middle of Liotrix not seen in Zelrix. **Strength:** Multiple with no numeric overlap (1/4,1/2,1,2,3) vs. single (6.5 mg over 4 hours) **Frequency of use:** daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Loprox (Ciclopirox) (Some formulations discontinued but generic equivalents are marketed.)	Look	0.77 % cream, topical suspension, and topical gel 1 % shampoo	Use a small amount topically to affected area daily	**Orthographic difference:** Loprox includes a 'p' providing a down stroke not seen in Zelrix and lacks an upstroke. **Dosage forms:** Multiple requiring a specific formulation when ordered or prescribed (cream, topical suspension and gel. and shampoo) vs. Iontopheretic Transdermal System or patch. **Frequency of Use:** daily vs. one time with a single repeat or use as directed.
Mentax (Butenafine	Look	1 % cream *(single strength)*	Apply a small amount topically to affected area daily.	**Orthographic difference:** Mentax appears longer when scripted and includes the letter 't' providing a cross stroke in the middle of the name. **Dosage form:** cream vs. Iontopheretic Transdermal System or patch **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Mobic (Meloxicam)	Look	7.5 mg and 15 mg tablets 7.5 mg/5 mL oral suspension	One tablet or teaspoon (7.5 mg) by mouth daily	**Orthographic difference:** Mobic appears shorter when scripted and Zelrix ends with an 'x' providing a cross stroke. **Strength:** multiple with no numeric overlap (7.5 mg, 15 mg and 7 5 mg/ 5 mL) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Serax (oxazepam)	Look and Sound	10 mg, 15 mg and 30 mg capsules	One capsule by mouth three times or four times daily.	**Orthographic difference:** Zelrix includes the letter 'l" which provides an upstroke in the middle of the name. **Phonetic difference:** Serax includes a first syllable with a long 'ee' sound and no concluding consonant sound. **Strength:** multiple - 10 mg, 15 mg and 30 mg vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Oral capsules vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** three times or four times daily vs. one time with a single repeat or use as directed.
Solurex (Dexamethasone Sodium Phosphate) (Discontinued branded generic product with equivalent products marketed)	Sound	20 mg/5 mL, 40 mg/10 mL, and 120 mg/30 mL (4 mg/mL) injection in vials	Adults 10 mg intravenously or intramuscularly *one time* or 4 mg intravenously every six hours. Pediatrics: 0.06 mg/kg to 0.3 mg/kg divided into four doses intravenously every six hours.	**Phonetic difference:** Solurex includes a third syllable which is an added vowel sound in the middle of the name. **Strength:** multiple - 20 mg/ 5 mL, 40 mg/10 mL, and 120 mg/30 mL vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Injection for intravenous or intramuscular use vs. Iontopheretic Transdermal System or patch applied topically.
Sprix (Ketoralac)	Sound	15.75 mg/ actuation *(single strength)*	One or two sprays intranasal every six to eight hours.	**Phonetic difference:** Sprix includes only one syllable and begins with a mixed consonant sound 'Spr-.' **Dosage form and route of administration:** Nasal Spray vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** every six to eight hours vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Taclonex (Calcipotriene and Betametasone Diproprionate)	Look	0.005%/0.064% ointment or topical suspension *(single strength)*	Apply a small amount to affected area topically daily.	**Orthographic difference:** Taclonex includes eight letters, two more than Zelrix, which provide added length when scripted. **Dosage form:** Ointment or topical suspension vs. Iontopheretic Transdermal System or patch **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Valtrex (Valacyclovir)	Look and Sound	500 mg and 1000 mg tablets	One or two tablets (1000 mg) by mouth three times.	**Orthographic difference:** Valtrex includes the letter 't' providing an additional upstroke as well as a cross stroke in the middle of the name. **Phonetic difference:** Valtrex begins with a different sounding consonant ('v' vs. 'Z') and the beginning consonant sound of the second syllable differs ('tr' vs. 'rr'). **Strength:** multiple - 500 mg and 1000 mg vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Three times daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Xanax (Alprazolam)	Sound	0.25 mg, 0.5 mg, 1 mg and 2 mg tablets: XR - 0.5 mg, 1 mg, 2 mg, and 3 mg extended-release tablet	One immediate release tablet (0.25 mg to 2 mg) by mouth three times daily. One extended-release tablet (0.5 mg to 3 mg) by mouth daily.	**Phonetic difference:** Zelrix includes a first syllable that concludes with a consonant sound 'll' and the beginning consonant of the second syllable sounds different than that in Zelrix ('rr' vs. 'nn'). Xanax may include a modifier "X" "R" providing two additional syllables. **Strength:** multiple - 0.25 mg, 0.5 mg, 1 mg, 2 mg and 3 mg vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zanaflex (Tizanidine)	Sound	2 mg, 4 mg, and *6 mg* capsules 2 mg and 4 mg tablets	One or two tablets or capsules (2 mg to 8 mg) by mouth every six to eight hours. Not to exceed 24 mg in 24 hours.	**Phonetic difference:** Zanaflex includes three syllables and the last syllable begins with a different sounding consonant ('fl' vs. 'r') **Dosage form and route of administration:** Oral tablets and capsules vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** every six to eight hours vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zebeta (Bisoprolol)	Look	5 mg and 10 mg tablets	One half to one tablet (2.5 mg to 10 mg) by mouth daily.	**Orthographic difference:** Zebeta includes the letter 't' providing an additional upstroke and a cross stroke in the fifth position. **Strength:** multiple - 5 mg and 10 mg vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zelapar (Selegiline)	Look	1.25 mg orally disintegrating tablets *(single strength)*	One or two tablets (1.25 mg to 2.5 mg) dissolved in the mouth daily.	**Orthographic difference:** Zelapar appears longer when scripted and includes the letter 'p' providing a down stroke. **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zelnorm (Tegaserod)	Look	6 mg tablets (Single strength)	One tablet (6 mg) by mouth twice daily.	**Orthographic difference:** Zelnorm ends with an extra letter 'm' providing added length to the name when written. **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed. Zelnorm is only available through compassionate use from the Food and Drug Administration secondary to safety concerns.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zentrip (Meclizine HCl)	Look	25 mg oral dissolving strip *(single strength)*	One or two strips (25 mg to 50 mg) dissolved in the mouth once daily.	**Orthographic difference:** Zentrip includes an additional letter adding length when scripted and the 't' provides a cross stroke in the middle of the name. **Dosage form and route of administration:** Oral dissolving strip vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zerit (Stavudine)	Look	15 mg, 20 mg, 30 mg and 40 mg capsules 1 mg/ mL oral solution	Adults 20-40 mg (one capsule) by mouth twice daily Children 30-60 kg 30 mg (one capsule or 30 mL) by mouth daily < 30 kg: 1 mg/kg by mouth daily. Neonates up to 14 days old: 0 5 mg/kg by mouth daily.	**Orthographic difference:** Zerit ends with the letter 't' providing an upstroke at the end of the name rather than the middle. **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zetia (Ezetimibe)	Look	10 mg tablets *(single strength)*	One tablet (10 mg) by mouth daily.	**Orthographic difference:** Zetia includes a letter 't' in the middle of the name providing a cross stroke. **Dosage form and route of administration:** Oral tablets vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zofran (Ondansetron)	Look	4 mg, 8 mg, and 24 mg tablet ODT - 4 mg and 8 mg orally disintegrating tablets 4 mg/2 mL vial 32 mg/50 mL bag 4 mg/5 mL oral solution	**Oral:** Highly Emetogenic Chemotherapy: Adults: 24 mg (one or three tablets) by mouth *one time* 30 minutes prior to Chemotherapy. Moderately Emetogenic Chemotherapy: Adults and pediatrics 12 years and older: 8 mg (one tablet or two teaspoons or 10 mL) by mouth three times daily starting 30 minutes prior to chemo until one or two days after completing chemo. Pediatric: 4 to 11 years: 4 mg (one tablet or teaspoon or 5 mL) by mouth three times daily starting 30 minutes prior to chemo until one or two days after completing chemo. Radiotherapy (total body or the abdomen) Adults: 8 mg (one tablet or two teaspoons or 10 mL) by mouth three times daily first dose each day one or two hours prior to treatment. Postoperative: Adults: 16 mg (two tablets or 20 mL or four teaspoons) by mouth *once* one hour before induction of anesthesia. **Injection:** Chemotherapy: Adults: 32 mg (one bag) intravenously once 30 minutes prior to chemo or 0.15 mg/kg intravenously 30 minutes prior to chemotherapy and four hours and eight hours after first dose. Pediatrics: 0.15 mg/kg intravenously 30 minutes prior to chemotherapy and four hours and eight hours after first dose. Postoperative: Adults: 4 mg *one time* immediately prior to induction of anesthesia.	**Orthographic difference:** Zofran includes the letter 'F' which may provide a cross stoke or a down stroke when scripted. **Strength:** multiple with no numeric overlap 4 mg, 8 mg, 24 mg, 4 mg/2 mL, 32 mg/50 mL, 4 mg/5 mL vs. single - 6.5 mg over 4 hours **Dosage form and route of administration:** oral tablets, oral disintegrating tablets, oral solution, and injection in vial and premade bag for intravenous administration vs. Iontopheretic Transdermal System or patch applied topically.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zoladex (Goserelin)	Look	3.6 mg and 10.8 mg implant in a prefilled syringe	Inject 3.6 mg (one syringe) subcutaneously once a month. Inject 10.8 mg (one syringe) subcutaneously once every three months. *May be ordered as a one time dose*	**Orthographic difference:** Zoladex includes an extra letter making the name appear longer when scripted and includes the letter 'd' providing an additional upstroke. **Strength:** multiple with no numeric overlap (3.6 mg and 10.8 mg) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** Subcutaneous implant vs. Iontopheretic Transdermal System or patch applied topically.
Zolinza (Vorinostat	Look	100 mg capsule (Single strength)	Three to four capsules (300 mg to 400 mg) by mouth daily. May be limited to five days a week depending on adverse events.	**Orthographic difference:** Zolinza includes an extra letter providing added length to the name and includes a lower case 'z' which may provide a down stroke when scripted. **Dose:** 300 mg or 400 mg (three or four capsules) vs. one patch or system **Dosage form and route of administration:** oral capsules vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be <u>omitted</u> during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zoloft (Sertraline)	Look	25 mg, 50 mg and 100 mg tablets 20 mg/mL oral solution	One tablet (25 mg - 100 mg) by mouth daily. oral solution dose is 1.25 mL to 5 mL or ¼ to one teaspoon)	**Orthographic difference:** Zoloft ends with the letters 'f' and 't' which provide additional upstrokes. **Strength:** multiple with no numeric overlap (25 mg, 50 mg, 100 mg, and 20 mg/mL) vs. single (6.5 mg over 4 hours) **Dosage form and route of administration:** Oral tablets and solution vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily vs. one time with a single repeat or use as directed.
Zolpimist (Zolpidem tartrate)	Sound	5 mg per actuation oromucosal spray *(single strength)*	Two sprays into the mouth at bedtime.	**Phonetic difference:** Zolpimist includes three syllables and two consonant sounds not heard in Zelrix ('pp' and 'mm'). **Dosage form and route of administration:** oromucosal spray to the mouth vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** daily, at bedtime vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zostrix (Capsaicin)	Look and Sound	0.025 % cream HP 0.075% cream Neurapathy 0.25% cream	Apply a sufficient amount to affected area two times daily, three times daily or four times daily.	**Orthographic difference:** Zostrix includes an extra letter provided added length when scripted and the letter 't' provides a cross stroke in the middle of the name. **Phonetic difference:** Zostrix includes a concluding consonant sound in the first syllable 'ss' and the beginning consonant sound of the second syllable differs ('tr' vs. 'rr'). **Strength:** multiple - 0.025%, 0.075%, 0.25% vs. single - 6.5 mg over 4 hours **Dosage form:** cream vs. Iontopheretic Transdermal System or patch **Frequency of use:** two times daily, three times daily or four times daily vs. one time with a single repeat or use as directed.
Zotex (Dextromethorphan, Guaifenesin, and Phenylephrine HCL)	Look	20 mg/100 mg/10 mg per 5 mL oral liquid Pediatric Drops 3 mg/35 mg/2.5 per mL EX 15 mg/350 mg/12 mg tablets Other formulations using the modifiers 12, 12D, C, D, and PE also identified in the Redbook but could not find in references to determine the labeling for dosing.	Oral liquid: 12 years and older: One Teaspoon (5 mL) by mouth every four hours. Not to exceed 30 mL in 24 hours. 6 years to < 12 years: One half teaspoon (2.5 mL) by mouth every four to six hours, not to exceed 15 mL. 2 years to < 6 years: one quarter teaspoonful (1 25 mL) by mouth every four to six hours, not to exceed 7.5 mL Pediatric drops 6 months to 9 months 0.75 mL by moth four times daily, 9 months to 18 months: 1 mL by mouth four times daily.	**Orthographic difference:** Zotex include fewer letters which provides for a shorter name when scripted and includes the letter 't' providing a cross stroke in the middle of the name. Zotex is a family or root name that often is followed by a modifier. **Dosage form and route of administration:** Oral liquid or tablet vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Every four hours vs. one time with a single repeat or use as directed.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Zelrix **(Sumatriptan)**		**6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to write the directions for use as "use as directed")**	
Zovirax (Acyclovir)	Look	200 mg capsule, 400 and 800 mg tablets, 200 mg/5 mL oral solution, 5% cream and ointment, 500 mg and 1000 mg vial for injection	Intravenous Adults and children 12 years and older: 10 mg/kg intravenously every 8 hours. Pediatric 3 months to <12 years: 20 mg/kg intravenously every 8 hours Neonates and infants < 3 month: 10 mg/ kg intravenously every eight hours Oral for adults: One capsule (200 mg) by mouth five times daily. One tablet (400 mg) by mouth five times daily or three times daily. One tablet (800 mg) by mouth Twice daily or three times daily. Topical: Apply a small amount topically to lesion five times daily.	**Orthographic difference:** Zovirax includes an extra letter providing added length when scripted and lacks any letters providing upstrokes. **Strength:** Multiple (200 mg, 400 mg, 800 mg, 200 mg/5 mL, 5%, 500 mg, and 1000 mg vs. 6.5 mg over 4 hours. **Dosage form:** Multiple (capsule, tablet, oral solution, cream, ointment, and powder for injection) vs. Iontopheretic Transdermal System **Frequency of use:** every eight hours up to five times daily vs. one time with a single repeat or use as directed.
Zyvox (Linezolid)	Look	600 mg tablet, 100 mg/5 mL oral suspension, 200 mg/100 mL and 600 mg/300 mL bag	Adult: 600 mg (one tablet by mouth and one bag intravenous infusion) twice daily. Pediatric: 10 mg/kg by mouth or intravenously twice daily.	**Orthographic difference:** Zyvox appears shorter when scripted, includes the letter 'y' providing a down stroke and lacks an upstroke. **Dosage form and route of administration:** Oral tablet and suspension and injection in a premade infusion bag for intravenous infusion vs. Iontopheretic Transdermal System or patch applied topically. **Frequency of use:** Twice daily vs. one time with a single repeat or use as directed.

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

Proposed name: **Zelrix** **(Sumatriptan)**	**Strength:** **6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be omitted during the procurement and prescription steps of the medication use process)**	**Usual dose:** **Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to be write the directions for use as "use as directed")**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode (name confusion)**
Librax (Chlordiazepoxide HCL and Clindium Br) 5 mg/2.5 mg capsules Usual dose: one to two capsules by mouth before meals and at bedtime.	Orthographic similarity: Both names contain six letters providing similar length, the first letter in each name (L vs. Z) may appear similar when scripted, the remaining five letters (-ibrax vs. -elrix) provide an upstroke in the same position and end with the letter 'x' which makes these groups appear the same when scripted. Both products are available in a single strength.	Although strong orthographic similarity, the differences in product characteristics minimize the potential for medication errors. *Rationale:* Librax is an oral capsule taken up to four times daily (before meals and at bedtime). Preliminary drug use data suggests prescribers include directions for prescriptions for Librax. Finally, the drug use data suggests the dispensing quantity for Librax is noted to be more than the proposed 3, 4 or 6 for Zelrix. Zelrix is a topically applied Iontopheretic Transdermal System or patch applied once at on set of headache which may repeat one time but not to exceed two systems in 24 hours.

Proposed name: **Zelrix** **(Sumatriptan)**	**Strength:** **6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be <u>omitted</u> during the procurement and prescription steps of the medication use process)**	**Usual dose:** **Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to be write the directions for use as "use as directed")**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode (name confusion)**
Selsun (Selenium Sulfide) 2.5% shampoo Usual dose: Apply sufficient amount to lather and rinse twice weekly. (Discontinued product with generic equivalents available.)	Orthographic similarity: Both names include six letters, the First letters may appear as mirror images (S vs. Z), and the second and third letters are the same '-el-.' Both products have a single strength and are applied topically.	Orthographic difference and use in clinical practice minimize the risk of name confusion resulting in medication error. *Rationale:* Orthographic difference stems from the fact Zelrix ends with the letter 'x' which includes a cross stroke not seen in Selsun. Selsun is a prescription shampoo product used twice weekly for the treatment of severe dandruff. Zelrix is a large patch-like device applied to the upper arm or upper leg for the treatment of migraine headaches and applied once at on set of headache which may repeat one time but not to exceed two patches in 24 hours.
Zerlor (Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate) 712.8 mg/60 mg/32 mg tablets Usual dose: One tablet by mouth every four hours, not to exceed 5 tablets in 24 hours.	Orthographic similarity: Both names contain six letters and begin with the same two letters "Ze-," and both names include the letter 'l' providing an upstroke in the middle of the name. Both products have a single strength and are indicated for the treatment of some type of pain.	Differentiating product characteristics minimize the risk of name confusion resulting in medication errors. *Rationale:* Zerlor is an oral combination opiate analgesic. These tablets are taken by mouth every four hours as needed for pain. Zelrix is a large patch-like device applied to the upper arm or upper leg for the treatment of migraine headaches and is applied at the onset. Zelrix will be packaged in cartons containing (b) (4) 6 patches. Preliminary drug use data suggests the use of Zerlor is limited and has been decreasing over the past few years.

Proposed name: **Zelrix** **(Sumatriptan)**	**Strength:** **6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be <u>omitted</u> during the procurement and prescription steps of the medication use process)**	**Usual dose:** **Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to be write the directions for use as "use as directed")**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode (name confusion)**
Zolvit (Hydrocodone Bitartrate and Acetaminophen) 10 mg/300 mg per 5 mL oral solution Usual dose: Adults (> 45 kg) 11.25 mL (2 1/4 teaspoons) by mouth every four to six hours. Children (12-15 kg): 2.8 mL by mouth every four to six hours (16-22 kg) 3.75 mL (3/4 teaspoon) by mouth every four to six hours (23-31 kg) 5.6 mL (one teaspoon) by mouth every four to six hours; (32-45 kg) 7.5 mL (1 and ½ teaspoons) by mouth every four to six hours	**Orthographic similarity:** Both names begin with the letter Z and contain six letters, both include a letter 'l' in the third position providing an upstroke and end with a letter providing a cross stroke (t vs. x). Both products have a single strength and are indicated for the treatment of some type of pain.	Use in clinical practice minimizes the risk of medication error. *Rationale:* The orthographic difference stems from the fact Zolvit ends with the letter 't' providing an additional upstroke. Zolvit is a combination oral opiate analgesic. This oral solution is taken by mouth every four to six hours. Zolvit is available in bottles containing 16 ounces (473 mL). Zelrix is a large patch-like device applied to the upper arm or upper leg for the treatment of migraine headaches and is applied and activated at the onset.

Proposed name: **Zelrix** **(Sumatriptan)**	**Strength:** **6.5 mg over 4 hours** **Iontopheretic Transdermal System** **(single strength product, thus the strength may be <u>omitted</u> during the procurement and prescription steps of the medication use process)**	**Usual dose:** **Apply one patch/system to upper arm or leg at onset of headache and activate. Leave in place for four hours. May apply second patch/system in 2 hours if not effective. Maximum dose of 2 patches in 24 hours.** **(Due to the complex nature of this system, prescribers are likely to be write the directions for use as "use as directed")**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode (name confusion)**
Zmax (Azithromycin) extended-release powder for oral suspension 2 gram bottle Usual dose: Adults: Take one (2 g) by mouth one time. Pediatrics : 60 mg/kg (maximum dose 2 g) by mouth one time.	Orthographic similarity; Both names begin and end with the same letters (Z and x) and have a short appearance. Both products have a single strength which can be omitted. Both products are administered once.	Orthographic difference as well as differentiating product characteristics minimize the risk name confusion would result in medication error. *Rationale:* Orthographic difference stems from the fact Zelrix includes the letter 'l' providing an upstroke not seen in Zmax. Zmax is an antibiotic powder for oral administration which requires reconstitution prior to dispensing. Zelrix is a large patch-like device applied topically to the upper arm or upper leg for the treatment of migraine headaches and is applied and activated at the onset.

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/s/

RICHARD A ABATE
03/09/2011

MELINA N GRIFFIS
03/09/2011

CAROL A HOLQUIST
03/09/2011