CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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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:	September 12, 2013
Reviewer(s):	Vicky Borders-Hemphill, Pharm.D. Division of Medication Error Prevention and Analysis
Team Leader:	Jamie Wilkins Parker, Pharm.D. Division of Medication Error Prevention and Analysis
Drug Name(s):	Evzio (Naloxone Hydrochloride Injection, USP)
Strength(s):	0.4 mg/0.4 mL
Application Type/Number:	NDA 205787
Applicant/Sponsor:	Intelliject
OSE RCM #:	2013-1762

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Evzio, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the July 17, 2013, request for proprietary name submission under NDA 205787:

- Proprietary name: Evzio
- Established name: naloxone hydrochloride injection, USP
- Indication:
  - (b) (4)
  - (b) (4)
- Route of administration: intramuscular or subcutaneous
- Dosage form: injection
- Dose: injection once into the anterolateral aspect (outer) of the thigh, through the clothing if necessary; if the desired degree of counteraction and improvement in respiratory function is not obtained, after 2-3 minutes, another dose may be administered.
- How Supplied: carton containing two pre-filled, single use naloxone auto-injectors (NAI) and a single NAI trainer; each NAI delivers 0.4 mg naloxone hydrochloride (0.4 mL) and is equipped with an electronic voice prompt system that provides audible instructions for use using voice commands and beeps and visual cues (red/green LED lights)
- Storage: Controlled room temperature 59°F to (b) (4)°F. Temperature excursions permitted between 39°F and 104°F. Do not refrigerate or freeze.
- Sponsor: Intellijject

2 RESULTS

The following sections provide the information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anesthesia,

Analgesia and Addiction Products (DAAAP) 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

This name does not contain a USAN Stem.[1]

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

Forty-three practitioners participated in DMEPA's prescription studies. Sixteen of the participants interpreted the name correctly as "Evzio", with correct interpretation occurring in the voice prescription and outpatient written studies. All eleven inpatient responses misinterpreted the name incorrectly as "Eozio". The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. DMEPA considered the various misinterpretations in our look-alike and sound-alike searches and analysis (see Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 26, 2013 e-mail, DAAAP did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters comprising the proposed proprietary name. These variations were used in the search for names similar to Evzio. Table 1 lists the names with potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Evzio identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines, the FDA Prescription Simulation, and by (b) (4). Our analysis of the forty-two names contained in Table 1 found none to be confused with proposed name.

[1] August 26, 2013 search of the United States Adopted Name (USAN) stems

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Enriav	FDA	(b) (4)	FDA	(b) (4)	FDA
Eraxis	FDA	Esgic	FDA	Inula	FDA
Evoxac	FDA	(b) (4)	FDA	Ismo	FDA
Frova	FDA	Esrar	FDA	Levsin	FDA
Auvi-Q	FDA	Estrace	(b) (4)	Lexapro	(b) (4)
Avinza	FDA	Essian	FDA	Ovace	FDA
Azia	FDA	Eurax	FDA	Ovcon	FDA
Cesia	FDA	Evion	FDA	Ovral	FDA
Ecoza	FDA	Evoclin	(b) (4)	Xigris	(b) (4)
Enjuvia	(b) (4)	EvoPro	FDA	Zovia	FDA
Errin	FDA	Exalgo	(b) (4)		
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Exo	FDA	Forteo	(b) (4)	Zetia	(b) (4)
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Avapro	FDA	Evista	Both	Invanz	Both
Entyvio***	FDA	Evzio	FDA	Zarzio***	FDA
Evac	FDA				

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DAAAP via e-mail August 26, 2013. At that time we also requested additional information or concerns that could inform our review. DAAAP did not convey additional concerns with the proposed proprietary name, Evzio.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

3.1 PROPRIETARY NAME COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your July 17, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

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

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

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [2]

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

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.[3]

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).

[3] 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.[4] 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

[4] 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name Evzio	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'E'	C, f	
Lower case 'e'	a, i, l, o, u,p	Any Vowel
Lower case "v"	r, u, z	f
Lower case 'z'	c, e, g, n, m, q, r, s, v	c, s, x
Lower case 'i'	e, l	y
Lower case "o"	a, c, e, u	Any Vowel
Letter strings in Name Evzio	**Scripted May Appear as**	**Spoken May Be Interpreted as**
zi	u	se, vi, ci, yi
ev		f, eb, ep, es

Appendix C: Prescription Simulation Samples and Results

Figure 1. Evzio Study (Conducted on August 9, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Evzio inject subcutaneous x1 prn	Evzio use as directed Dispense # 1
Outpatient Prescription: Evzio #1 UAD	

FDA Prescription Simulation Responses.

192 People Received Study

43 People Responded

Total	15	15	13	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
EBSEO	0	1	0	1
EBSIO	0	4	0	4
EBVIO	0	1	0	1
EBZIO	0	1	0	1
EOZIO	0	0	11	11
EPSEO	0	1	0	1
EPSIO	0	1	0	1
ESCIO	0	1	0	1
EUZIO	1	0	0	1
EVYIO	0	0	2	2
EVZIO	14	2	0	16
FEVIAL	0	1	0	1
FIZEO	0	1	0	1
F-SEO	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 Evzio	Failure preventions
1	Avinza	morphine sulfate	Orthographic	Pair have sufficient orthographic differences
2	Enjuvia	estrogens, conjugated synthetic B	Orthographic	Pair have sufficient orthographic differences
3	Entyvio***	vedolizumab	Orthographic and Phonetic	Pair have sufficient orthographic and phonetic differences
4	(b) (4) ***	levonorgestrel ethinyl estradiol	Orthographic	DMEPA found proposed name unacceptable in OSE Review 2010-2109/2107 (ANDA 91663) due to orthographic and similar product characteristics with currently marketed names
5	(b) (4) ***	levonorgestrel ethinyl estradiol	Orthographic	DMEPA found proposed name unacceptable in OSE review 2010-1646 (ANDA 200245) due to orthographic and similar product characteristics with currently marketed names
6	Esrar	marijuana	Orthographic	Name is alternative name for botanical product not likely to be written on a retail or hospital prescription and must be procured and dispensed through state approved medical marijuana registry programs and dispensaries
7	Estrace	estradiol	Orthographic	Pair have sufficient orthographic differences
8	Evoclin	clindamysin phosphate	Orthographic	Pair have sufficient orthographic differences
9	EvoPro	protein powder	Orthographic	Name is for a product line of protein powders not likely to be written on a prescription
10	Evzio	naloxone	Orthographic and Phonetic	Proprietary name that is the subject of this review

No.	Proprietary Name	Active Ingredient	Similarity to Evzio	Failure preventions
11	Evion	Vitamin E		international name (italy, greece, germany, india, indonesia, phillipines
12	Exalgo	hydromorphone hydrochloride	Orthographic	Pair have sufficient orthographic differences
13	Exo	Grape puree, blueberry puree, cranberry puree, various juice extracts	Phonetic	Pair have sufficient phonetic differences
14	Forteo	Teriparatide recombinant human	Phonetic	Pair have sufficient phonetic differences
15	Inula	elecampane	Orthographic	Scientific name for a several product that contain elecampane and is not likely to be written on a prescription
16	Invanz	ertapenem sodium	Orthographic	Pair have sufficient orthographic differences
17	Levsin	hyoscyamine	Orthographic	Pair have sufficient orthographic differences
18	Lexapro	escitalopram oxalate	Orthographic	Pair have sufficient orthographic differences
19	Zarzio***	filgrastim	Orthographic and Phonetic	DMEPA found proposed name unacceptable in OSE review #2012-265 (IND (b) (4)) due to orthographic and similar product characteristics with currently marketed names

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.

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Auvi-Q (epinephrine) **Strength:** 0.3 mg and 0.15 mg **Dosage form:** injection **Dose:** inject once into the anterolateral aspect of the thigh, through clothing if necessary **Route of Administration:** intramuscular and subcutaneous	Orthographic similarities: Both names have the same shape and length and contain prefixes ("Evz" vs. "Auv") that may appear similar when scripted and contain the letter "i" in the 4th position Product characteristic similarities: **Dose:** one injection **Frequency:** Once or UAD **Route of Administration**: intramuscular and subcutaneous	Orthographic differences: The last letter "Q" in Auvi-Q may help to differentiate these names and the infix "uv" in Auvi-Q may confer elongation Product characteristic differences: **Strength:** Evzio has a single strength which may be omitted from the prescription vs. Auvi-Q has multiple strengths which may need to be included and there is no overlap in strengths Writing samples requested

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Avapro (irbesartan) **Strength:** 75 mg, 150 mg, 300 mg **Dosage form:** tablet **Dose:** 150 mg to 300 mg once daily **Route of Administration:** oral	<u>Orthographic similarities:</u> Both names have the same shape and similar length and contain prefixes (“Ev” vs. “Av”), infixes (the letters “ap” may appear similar to the letter “z”), and suffices (“io” vs. “ro”) that may appear similar when scripted; <u>Phonetic similarities:</u> Both names begin with prefixes that may sound similar “Ev” vs. “Av” and end with the letter “o”	<u>Orthographic differences:</u> The suffix letters “pr” in Avapro may confer elongation <u>Phonetic differences:</u> Evzio infix “zi” does not sound similar to Avapro infix “apr” <u>Product characteristic differences:</u> **Strength:** Evzio has a single strength which may be omitted from the prescription vs. Avapro strength must be included on the prescription and there is no overlap in strengths **Frequency:** Once or UAD vs. once daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Azia (oscillococcinum; dilution of duck liver and heart extract) *An OTC homeopathic product most often sold as Oscillococcinum* **Strength:** N/A **Dosage form:** pellets in a tube **Dose:** contents of one tube three times daily **Route of Administration:** oral	Orthographic similarities: Both names begin with letters "E" vs. "A" and end with letter ""io" vs. "ia" that may appear similar when scripted and have similar shape and length Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Orthographic differences: The infix letters in the second position, "v" vs. "z", are not orthographically similar and may help to differentiate these names Product characteristic differences: **Frequency:** Once or UAD vs. three times daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Cesia (desogestrel/ethinyl estradiol) **Strength:** triphasic: 0.1 mg/25 mcg, 0.125 mg/25 mcg, 0.15/25 mcg **Dosage form:** tablet **Dose:** once daily or UAD **Route of Administration**: oral	Orthographic similarities: Both names have the same shape and length and begin with letters that may appear similar when scripted ("E" vs. "C"), contain prefix letters in the third position that may appear similar ("s" vs. "z"), and suffices ("io" vs. "ia") that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The infix letters in the second position, "v" vs. "e", are not orthographically similar and may help to differentiate these names

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Ecoza (econazole nitrate) **Strength:** 1% **Dosage form:** foam **Dose:** Apply topically to affected area once daily for four weeks or UAD **Route of Administration:** topical	Orthographic similarities: Both names have the similar shape and the same length and contain prefixes ("Ev" vs. "Ec") and end with letters "o" vs. "a" that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** UAD	Orthographic differences: The infixes "zi" vs. "oz" are not similar when scripted Product characteristic differences: **Dose:** one injection vs. apply to affected area

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Enriav (tinvantinib) **Strength:** 120 mg **Dosage form:** tablet **Dose:** 120 mg, 240 mg, or 360 mg twice daily (max 720 mg /day) **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and length and contain prefixes (“Ev” vs. “En”) and suffices (“zio” vs. “ria”) that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Orthographic differences: The last letter “v” in Enriav may help to differentiate these names as the letters “iav” confer elongation Product characteristic differences: **Frequency:** Once or UAD vs. twice daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Eraxis (anidulafungin) **Strength:** 50 mg and 100 mg **Dosage form:** infusion **Dose:** 200 mg loading dose on day 1 followed by 100mg once daily for 14 days; or 100 mg loading dose on day 1 followed by 50 mg once daily for 14 days **Route of Administration:** intravenous	<u>Orthographic similarities:</u> Both names have the same shape and similar length and contain prefixes ("Ev" vs. "Er") that may appear similar when scripted	<u>Orthographic differences:</u> The suffix "zio" is not similar to "axis" when scripted <u>Product characteristic differences:</u> **Strength:** Evzio has a single strength which may be omitted from the prescription vs. Eraxis has multiple strengths which may need to be included on the prescription and there is no overlap in strengths **Frequency:** Once or UAD vs. once daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Errin (norethindrone) **Strength:** 0.35 mg **Dosage form:** tablet **Dose:** once daily or UAD **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and length and contain prefixes ("Ev" vs. "Er") and suffices ("zi" vs. "ri") that may appear similar when scripted Product characteristic similarities: **Strength:** Evzio has a single strength which may be omitted from the prescription Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The suffix letters in the last position, "o" vs. "n", are not orthographically similar and may help to differentiate these names

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
(b) (4) (levonorgestrel/ethinyl estradiol) **Strength:** 0.15 mg/0.03 mg **Dosage form:** tablet **Dose:** once daily or UAD **Route of Administration:** oral	Orthographic similarities: (b) (4) Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: (b) (4)

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Esgic (acetaminophen/butalbital/caffeine) **Strength:** 325 mg/50 mg/40 mg **Dosage form:** capsules and tablets **Dose:** one to two tablets every 4 hours as needed **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and length and contain prefixes (“Ev” vs. “Es”) and suffices (“zio” vs. “gic”) that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Product characteristic differences: **Frequency:** Once or UAD vs. every 4 hours

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Essian (esterified estrogens/methyltestosterone) **Strength:** 1.25 mg/2.5 mg **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and similar length, begin with the letter "E", and contain suffix letters ("io" vs. "ia") that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The infixes letters "vz" and "ss" are not similar when scripted and the last letter "n" in Essian confers elongation

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Eurax (crotamiton) **Strength:** 10% **Dosage form:** lotion or cream **Dose:** once or UAD **Route of Administration:** topical	Orthographic similarities: Both names have the same shape and length and contain prefixes ("Evz" vs. "Eur") that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The suffices ("io" vs. "ax") are not similar when scripted

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Evac (psyllium) **Strength:** 480 grams **Dosage form:** powder **Dose:** UAD **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and similar length and contain prefixes "Ev" Phonetic similarities: Both names begin with the prefix "Ev" that sounds similar Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** UAD	Orthographic differences: The suffix "zio" confers elongation and is not similar to "ac" when scripted Phonetic differences: The suffices "zio" vs. "ac" do not sound similar

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Evoxac (cevimeline hydrochloride) **Strength:** 30 mg **Dosage form:** capsule **Dose:** 30 mg three times daily **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and similar length and contain prefixes "Ev" Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Orthographic differences: The suffix "zio" vs. "oxac" are not similar when scripted as the "oxac" in Evoxac confers elongation Product characteristic differences: **Frequency:** Once or UAD vs. three times daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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

(b) (4)

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Frova (frovatriptan succinate) **Strength:** 2.5 mg **Dosage form:** tablet **Dose:** Once or UAD **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and length and begin with the prefixes “Ev” vs. “Fr” and end with suffixes “io” and “va” that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The infix letters “z” and “o” are not similar when scripted

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Ismo (isosorbide mononitrate) *withdrawn FR effective 7-8-2011 but generics are available* **Strength:** 20 mg **Dosage form:** tablet **Dose:** twice daily; no dosage adjustment for renal or liver **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and similar length and begin with orthographically similar letters "E" vs. "I" and both end in with the letter "o" Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Orthographic differences: The infix letters "vzi" do not appear similar to the letters "sm" when scripted Product characteristic differences: **Frequency:** Once or UAD vs. twice daily

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Ovace (sulfacetamide) **Strength:** 10% **Dosage form:** foam, shampoo, cream, jelly **Dose:** Apply to affected area twice daily (foam and cream) or once or twice weekly (shampoo) or as directed or UAD **Route of Administration:** topical	<u>Orthographic similarities:</u> Both names have the same shape and length and begin with prefixes “Ev” vs. “Ov”, and suffices “io” vs. “ce” that may appear similar when scripted <u>Product characteristic similarities:</u> **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	<u>Orthographic differences:</u> The infix letters “z” and “a” are not similar when scripted <u>Product characteristic differences:</u> **Dosage form:** Evzio has a single dosage form which may be omitted form the prescription vs. Ovace which has multiple dosage forms which must be included **Frequency:** Once or UAD vs. twice daily of once or twice weekly

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Ovcon (norethindrone/ethinyl estradiol) **Strength:** 0.4 mg/35 mcg **Dosage form:** tablet **Dose:** once daily or UAD **Route of Administration:** oral	Orthographic similarities: Both names have the same shape and length and begin with prefixes “Ev” vs. “Ov” that may appear similar when scripted Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The suffixes “zio” vs. “con” are not similar when scripted

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Ovral (ethinyl estradiol/ norgestrel) **Strength:** 0.05 mg/0.5 mg **Dosage form:** tablet **Dose:** once daily or UAD **Route of Administration:** oral	<u>Orthographic similarities:</u> Both names have similar shape and the same length and begin with prefixes "Ev" vs. "Ov", and suffixes letters in third position, "z" vs. "r", that may appear similar when scripted <u>Product characteristic similarities:</u> **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	<u>Orthographic differences:</u> The suffixes "io" vs. "al" are not similar when scripted

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Xigris (drotrecogin alfa) **Strength:** 5 mg/vial and 20 mg/vial **Dosage form:** injection **Dose:** 24 mcg/kg/hr (70 kg: 1,680 mcg/hr) **Route of Administration:** intravenous	<u>Orthographic similarities:</u> Both names have similar shape and length and begin with prefixes “Ev” vs. “Xi”, and infixes “zi” vs. “gr” that may appear similar when scripted	<u>Orthographic differences:</u> The suffix “is” in Xigris may help differentiate these names and confers elongation <u>Product characteristic differences:</u> **Strength:** Evzio has a single strength which may be omitted from the prescription vs. Xigris has multiple strengths which may need to be included on the prescription and there is no overlap in strengths **Frequency:** Once or UAD vs. infusion rate

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Zetia (ezetimibe) **Strength:** 10 mg **Dosage form:** tablet **Dose:** one tablet once daily **Route of Administration:** oral	Phonetic similarities: Both names contain the letter "e" with the short 'e' sound in the prefix and have suffixes "io" vs. "ia" that may sound similar Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Phonetic differences The letter "z" does not sound like the letter "t" as placed in the prefix. Product characteristic differences: **Frequency:** Once or UAD vs. once daily
Zovia (ethynodiol diacetate/ethinyl estradiol) **Strength:** 1 mg/35 mcg **Dosage form:** tablet **Dose:** Once or UAD **Route of Administration:** oral	Orthographic similarities: Both names end with suffixes that may appear similar when scripted "zio" vs. "via" Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths **Frequency:** Once or UAD	Orthographic differences: The prefix "Ev" is not similar to "Zo" when scripted

Evzio (naloxone hydrochloride pre-filled autoinjector) **Dosage Form(s):** injectable **Strength(s):** 0.4 mg **Usual Dose:** once or use as directed **Route of Administration:** Intramuscular or Subcutaneous	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
Evista (raloxifene hydrochloride) **Strength:** 60 mg **Dosage form:** tablet **Dose:** 60 mg once daily **Route of Administration:** oral	Orthographic similarities: Both names begin with the prefix "Ev". Product characteristic similarities: **Strength:** Both products have a single strength which may be omitted from the prescription and there is no overlap in strengths	Orthographic differences: The infix and suffix letters "zio" is not similar in length or shape to "ista" when scripted Product characteristic differences: **Frequency:** Once or UAD vs. once daily

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

/s/

BRENDA V BORDERS-HEMPHILL
09/12/2013

JAMIE C WILKINS PARKER
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