CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205874Orig1s000

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:	February 7, 2014
Reviewer:	Jean Olumba, MD, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	Julie Neshiewat, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Zerenex (Ferric Citrate Coordination Complex) Tablets, 1 g
Application Type/Number:	NDA 205874
Applicant/Sponsor:	Keryx Biopharmaceuticals, Inc.
OSE RCM #:	2013-2661

*** 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, Zerenex, 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 November 18, 2013 proprietary name submission.

- Active Ingredient: Ferric Citrate Coordination Complex
- Indication of Use: Control of serum phosphorus levels and the increase in (b) (4) patients with chronic kidney disease on dialysis
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 1 g
- Dose and Frequency: Starting dose is (b) (4) 2 g orally 3 times per day with meals. The dose can be increased or decreased by 1 g to 2 g per day at 2 to 4 week intervals as needed to maintain serum phosphorus at recommended target levels (3.5 to 5.5 mg/dL), up to a maximum dose of 12 g daily. (b) (4)
- How Supplied: 200 tablets in 400-cc high-density polyethylene bottles
- Storage: Store at 20 to 25°C (68 to 77°F): excursions permitted to 15° to 30°C (59°F to 86°F) [See USP controlled room temperature]. Protect from moisture.
- Container and Closure Systems: The bottles are sealed with (b) (4) caps.

2 RESULTS

The following sections provide 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 Cardiovascular and Renal Products (DCRP) 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

There is no USAN stem present in the proposed proprietary name.[1]

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Zerenex, is not derived from any one particular concept. This proprietary name is comprised of a single word that does not contain any components such as a modifier, route of administration, dosage form, etc. that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Sixty practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products or any products in the pipeline. However, thirteen participants in the voice study misinterpreted the vowel 'E' as the vowel 'A'. One participant in the written inpatient study misinterpreted the vowel 'E' as the vowel 'A'. Three participants in the written outpatient study misinterpreted the consonant 'Z' for either the consonant 'L' or 'T'. We have considered these variations 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, November 18, 2013 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Zerenex. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Zerenex identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

[1] USAN stem list searched November 27, 2013.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar (n=13)					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Zurase	EPD	(b) (4)	EPD	Serenex	EPD
Gamunex	EPD	Generix-T	EPD	Zanosar	EPD
Zervalx	EPD	Veregen	EPD	Xerese	EPD
Zerit XR	EPD	Ranexa	EPD	Regranex	EPD
Cerumenex	EPD				
Sound Similar (n=4)					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Cerebyx	EPD	Zanaflex	EPD	Generess Fe	EPD
Clarinex	EPD				
Look and Sound Similar (n=9)					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Seradex	EPD	Desenex	EPD	Cervarix	EPD
Zerene	EPD	Zenapax	EPD	Xopenex	EPD
Serenex	EPD	Larynex	EPD	Xanax	EPD

Our analysis of the 26 names contained in Table 1 determined 26 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on January 23, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on January 30, 2014 they stated no additional concerns with the proposed proprietary name, Zerenex.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Karen Bengtson, OSE Project Manager, at 301-796-3338.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 18, 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. ***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.

10. ***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.

11. ***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.

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

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

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

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

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

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

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

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

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

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

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

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

18. ***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.

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

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

APPENDICES

Appendix A

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

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

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

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

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

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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.

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

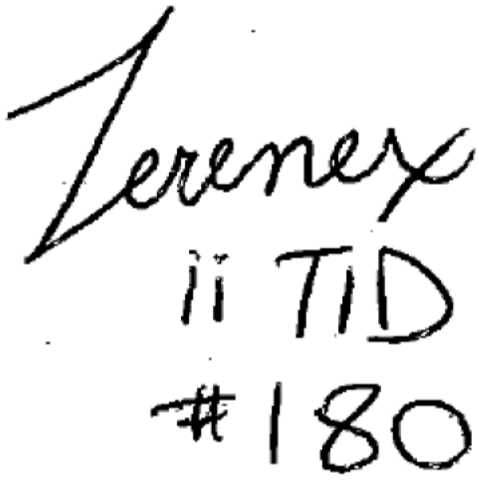
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Zerenex	Scripted May Appear as	Spoken May Be Interpreted as
Uppercase 'Z'	B, C, F, I, L, M, T, S, V, Y, P, X	C,S, X
Lowercase 'z'	c, e, g, n, m, q, r, s, v	c, s, x
Lowercase 'e'	a, c, i, l, o, u, p	Any vowel, y
Lowercase 'r'	s, n, e, v	
Lowercase 'n'	m, u, x, r, h, s	dn ,gn, kn, mn, pn, m
Lowercase 'x'	a, d, k, n, p, r, t, v, y	ks, kz, s, z
Letter String in Zerenex	**Scripted May Appear as**	**Spoken May Be Interpreted as**
er, re	v, u	ry
ere	w	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Zerenex Study (Conducted on November 29, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: (b) (4)	Zerenex Two by mouth three times daily # 180
Outpatient Prescription: 	

FDA Prescription Simulation Responses

192 People Received Study
60 People Responded

Study Name: Zerenex

Total	23	17	20	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
LERENEX	1	0	0	1
TERENEX	2	0	0	2
XERANAX	0	1	0	1
XERANEX	0	2	0	2
ZARANEX	0	2	0	2
ZARENEX	0	1	0	1
ZERANEX	0	6	0	6
ZERENAX	0	0	1	1
ZERENEX	20	3	19	42
ZURANEX	0	1	0	1
ZURYNEX	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 Zerenex	Failure preventions
1.	Cerumenex	Triethanolamine polypeptide oleate	Orthographic	The name pair has sufficient orthographic differences.
2.	Generess-Fe	Ethinyl Estradiol and Ferrous Fumerate and Norethindrone	Phonetic	The name pair has sufficient phonetic differences.
3.	Regranex	Becaplermin	Orthographic	The name pair has sufficient orthographic differences.
4.	Ranexa	Ranolazine	Orthographic	The name pair has sufficient orthographic differences
5.	Serenex	Valeriana Officinalis	Orthographic and Phonetic	An international product marketed in Canada. The Applicant was notified via e-mail of this information and responded to proceed with evaluating the name Zerenex.
6.	Veregen	Sinecatechins	Orthographic	The name pair has sufficient orthographic differences.
7.	Zanaflex	Tizanidine hydrochloride	Phonetic	The name pair has sufficient phonetic differences.
8.	Zanosar	Streptozocin	Orthographic	The name pair has sufficient orthographic differences.
9.	Zerene	Zaleplon	Orthographic and Phonetic	An international product marketed in several countries. The Applicant was notified via e-mail of this information and responded to proceed with evaluating the name Zerenex.
10.	Zerit XR	Stavudine	Orthographic	The name pair has sufficient orthographic differences.
11.	Zurase	Polyethylene glycol-modified uricase	Orthographic	This is an Orphan drug. 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: Zerenex** **(Ferric Citrate Coordination Complex)** **Dosage Form(s): Tablets** **Strength: 1 g** **Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals** **Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)**	**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.	Cerebyx (Fosphenytoin Sodium) Solution for Injection **Strength**: 50 mg PE/mL **Dose:** **Seizure, During neurosurgery: Treatment and Prophylaxis:** LD: 10mg to 20 mg phenytoin sodium equivalents (PE)/kg given IV or IM at a MAX IV rate of150 mg PE/min: **Status epilepticus:** LD: 15mg to 20 mg phenytoin sodium equivalents (PE)/kg IV at a rate of 100 mg to 150 mg PE/min	**Phonetic:** Both names have three syllables with similar sounding first and second syllables. In the third syllable, the letter pair ‘’ex’ in Zerenex and ‘yx’ in Cerebyx sound similar **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage:** There is potential for overlap of 1 g (50 kg patient receiving 20 mg/kg) or 2 g (100 kg patient receiving 20 mg/kg)	**Phonetic:** The third syllable starts the consonant ‘n’ in Zerenex and ‘b’ in Cerebyx which sounds different thereby differentiating both names **Frequency of administration**: There are no overlaps in administration frequency: Continuous Infusion vs. TID **Route of administration:** Intravenous or intramuscular vs. Oral

No.	**Proposed name: Zerenex** **(Ferric Citrate Coordination Complex)** **Dosage Form(s): Tablets** **Strength: 1 g** **Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals** **Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)**	**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.	Cervarix (Human Papillomavirs Recombinant Vaccine Bivalent (Types 16,18)) Suspension **Strength**: 0.5 ml **Dose:** 0.5 mL intramuscularly for 3 doses at 0, 1 to 2, and 6 months	**Orthographic:** The beginning letter strings 'Zer' and 'Cer' look similar when scripted. Both names end with the letter 'x' **Phonetic:** Both names have three syllables with similar sounding first and third syllables. **Strength:** Both products are single strength, and therefore can be omitted from the prescription.	**Orthographic:** The letter strings 'en' in Zerenex and 'var' in Cervarix look different when scripted. **Phonetic:** The middle syllable 'en' in Zerenex and 'var' in Cervarix produce different sounds which differentiates both names **Dosage:** There are no overlaps in dosage 0.5 ml vs. 1 g to 4 g. **Frequency of administration**: Single doses vs. three times daily.

No.	**Proposed name: Zerenex** **(Ferric Citrate Coordination Complex)** **Dosage Form(s): Tablets** **Strength: 1 g** **Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals** **Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)**	**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.	Clarinex (Desloratadine) Oral Syrup; Tablet **Strength:** Oral Syrup: 0.5 mg/mL Tablet: 5 mg **Dose:** 5 mg orally once daily	**Orthographic:** The beginning letter pairs 'Ze' and 'Cl' can look similar when scripted. The letter string 'ren' in Zerenex and 'rin' in Clarinex looks similar when scripted. Both names end with the letter pair 'ex'. **Phonetic:** Both names have three syllables with the same sounding third syllable. The second syllable also sounds similar. **Dosage/Dosage form:** Both can be prescribed as '1 tablet' **Route of administration:** Both are administered orally	**Orthographic:** The letter 'a' in Clarinex lengthens the prefix when compared to Zerenex. **Phonetic:** The first syllable 'Zer' and 'Cla' has the vowel 'e' and 'a' at different positions which displaces the sound produced. **Strength:** There are no overlaps in strength between the two products. **Frequency of administration**: QD vs. TID

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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.	Desenex (Clotrimazole) Topical Cream **Strength:** 1% **Dose:** Apply thin layer twice daily for up to 4 weeks	**Orthographic:** The letter pair 'er' in Zerenex and 'es' in Desenex look similar and both names end with 'enex'. **Phonetic:** Both names have three syllables with the same sounding second and third syllable. **Strength:** Both products are single strength, and therefore can be omitted from the prescription.	**Orthographic:** The beginning letter 'Z' and 'D' look different when scripted. **Phonetic:** The first syllable begins with the consonant 'Z' and 'D' which have different sounds that differentiate both names. **Dosage:** There are no overlaps in dosage Apply thin layer vs. 1 g to 4 g

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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.	Gamunex (Immune Globulin) Solution for Injection **Strength:** 100 mg/mL **Dose:** **Idiopathic thrombocytopenic purpura**: 400 mg/kg IV (4 mL/kg) once daily for 5 days OR 1000 mg/kg IV (10 mL/kg) once daily for 2 days for a total dose of 2 g/kg. **Primary immune deficiency disorder:** 300 to 600 mg/kg IV once every 3 to 4 weeks	**Orthographic:** Lower case letter pair 'ze' in Zerenex and lower case letter pair 'ga' can look similar when scripted. The letter strings 'enex' in Zerenex and 'unex' in Gamunex can look similar when scripted **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage:** There is an overlap in dosage 1000 mg/kg vs. 1000 mg **Route of administration:** The route can be omitted since Gammunex is only administered intravenously and Zerenex is administered orally.	**Orthographic:** The letter 'm' in Gamunex adds length to the infix compared to the letter 'r' in Zerenex. **Frequency of administration**: Once daily or once every 3 to 4 weeks vs. three times daily.

No.	**Proposed name: Zerenex** **(Ferric Citrate Coordination Complex)** **Dosage Form(s): Tablets** **Strength: 1 g** **Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals** **Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)**	**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.	Generix-T (Iron and Minerals and Vitamins) Tablet **Dose:** 1 tablet orally daily	**Orthographic:** Lower case letter pair 'ze' in Zerenex and lower case letter pair 'ge' in Generix-T can look similar when scripted. The letter strings 'renex' in Zerenex and 'nerix' in Generix-T look similar when scripted **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage/Dosage form:** Both can be prescribed as '1 tablet' **Route of administration:** Both are administered orally	**Orthographic:** If written with the modifier, the extra letter 'T' in Generix-T lengthens the name differentiating it from Zerenex. **Frequency of administration**: Once daily vs. three times daily.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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.	Larynex (Benzocaine) Lozenges **Strength:** 11 mg **Dose:** Use at least 3 or 4 more discs during the day as needed. Before bedtime, use 2 discs, placing one on each side of the mouth.(Max dose: 16/day)	**Orthographic:** The beginning letter strings 'Zer' and 'Lar' look similar when scripted. Both names end with same letter string 'nex'. **Phonetic:** Both names have three syllables with similar sounding second ('e' and 'y') and third ('nex') syllables. The letter pair in the first syllable 'er' in Zerenex and 'ar' in Larynex sounds similar. **Dosage:** Both can be prescribed as a dose of '1' **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Route of administration:** Both are administered orally **Frequency of administration**: Both products can be administered three times a day.	**Orthographic:** Larynex has a down stroke letter 'y' which differentiates both names. **Phonetic:** The onset of the first syllable 'Z' in Zerenex and 'L' in Larynex produces a sound that differentiates both names.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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.	Lovenox (Enoxaparin Sodium) Injection **Strength(s):** 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/mL, 120 mg/0.8 mL, 150 mg/mL, 300 mg/3 mL **Dose: DVT Prophylaxis**: 30 mg SUBQ every 12 hours. 40 mg SUBQ every 24 hours. Pediatrics: 0.5 mg/kg to 0.75 mg/kg SUBQ every 12 hours. **DVT Treatment:** 1 mg/kg SUBQ every 12 hours or 1.5 mg/kg SUBQ every 24 hours. Pediatrics: 1 mg/kg to 1.5 mg/kg SUBQ every 12 hours. **STEMI:** 30 mg intravenous bolus plus 1 mg/kg SUBQ every 12 hours or 0.75 mg/kg SUBQ every 12 hours **Renal dosing: CrCl < 30 mL/minute:** **DVT Prophylaxis**: 30 mg SUBQ once daily. **DVT Treatment:** 1 mg/kg SUBQ once daily **STEMI:** 30 mg intravenous bolus plus 1 mg/kg SUBQ once daily or 1 mg/kg SUBQ once daily	**Orthographic:** The first letter 'Z' and 'L' may look similar. Both names contain an 'n' at the fifth position and an 'x' at the last position. **Dosage:** There is numerical similarity in dosage. Lovenox 100 mg vs. Zerenex 1 g or 1000 mg.	**Orthographic:** The sequence of the vowels in between the consonants ('e-e-e' vs. 'o-e-o') can look different when scripted. Additionally, the letter pair 'ov' and 'er' look different when scripted. **Frequency of administration**: Once daily or Twice daily vs. Three times daily. **Route of administration:** Intravenous or Subcutaneous vs. Oral.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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.	Seradex (Brompheniramine Maleate and Carbetapentane Citrate and Phenylephrine Hydrochloride) Oral Solution **Strength:** 30 mg-10 mg-6 mg/5mL **Dose:** 5 mL to 10 mL orally every 12 hours.	**Orthographic:** The letter strings 'Zere' in Zerenex and 'Sere' in Seredex look similar when scripted. Both names end with the same letter pair 'ex' **Phonetic:** The letter string 'Zere' in Zerenex and 'Sere' in Seredex sounds similar. Both names end with the same sounding letter pair 'ex' **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage:** 5 mL to 10 mL vs. 1 g to 4 g There is numerical similarity between 10 mL and 1 g. **Route of administration:** Both are administered orally.	**Orthographic:** The upstroke letter 'd' in Seredex and 'n' in Zerenex are different when scripted.. **Phonetic:** The third syllable starts with the consonant letter 'n' in Zerenex and 'd' in Seredex which sounds different.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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	Xanax (Alprazolam) Tablets **Strength(s):** 0.25 mg, 0.5 mg, 1 mg, 2 mg **Dose:** 0.25 mg to 0.5 mg orally 3 times a day, may increase every 3 to 4 days if necessary; MAX daily dose, 4 mg in divided doses	**Orthographic:** The first letter 'Z' and 'X' can look similar when scripted. The letter strings 'enex' in Zerenex and 'anax' in Xanax look similar when scripted. **Phonetic:** The first syllables 'Ze' vs. 'Xa' sound similar when spoken. The ending syllable of both names also sound similar ('nax' vs. 'nex'). **Strength(s):** When written, there is a numerical overlap in the strength (Zerenex 1 g vs. Xanax 1 mg). **Route of administration:** Both are administered orally. **Dosage:** Both products can be prescribed as '1 tablet' **Frequency of administration:** Both products can be administered 'TID'.	**Orthographic:** The letter pair 'er' in Zerenex lengthens the prefix differentiating both names. **Phonetic:** Zerenex has three syllables while Xanax has two syllables. The letter pair 're' in Zerenex adds another syllable when spoken thereby differentiating both names. **Strength(s):** Although there is numerical overlap in the strength Zerenex 1 g vs. Xanax 1 mg, the units 'gram' and "milligram" sound different when spoken.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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	Xopenex (Levoalbuterol Hydrochloride) Solution for Inhalation **Strength(s):** 0.021 %, 0.042 %, 0.63 mg/3 mL, 1.25 mg/3 mL, 1.25 mg/0.5 mL **Dose:** Asthma: 1.25 mg to 2.5 mg oral inhalation every 20 min for 3 doses, then 1.25mg to 5 mg every 1-4 hours as needed Asthma: (bronchospasm), 0.63 mg to1.25 mg oral inhalation nebulized solution 3 times/day (every 6-8 hours) as needed	**Orthographic:** The beginning letter pairs 'Ze' and 'Xo' can look similar when scripted. Both names end with the same letter string 'enex' **Phonetic:** Both names have three syllables. The letter pair 'Ze' in Zerenex and 'Xo' in Xopenex sound different. The letter string 'enex' in both names sound similar. **Frequency of administration** Both products can be administered three times daily **Route of administration:** Both products are administered orally	**Orthographic:** The letter 'r' in Zerenex and 'p' in Xopenex are different when scripted, differentiating both names. **Phonetic:** The second syllable starts with the letter 'r' and 'p' which sounds different. **Strength:** There are no overlapping strengths. **Dosage:** There are no overlaps in dosage 0.63 mg to 2.5 mg vs. 1 g to 4 g.

No.	**Proposed name: Zerenex** **(Ferric Citrate Coordination Complex)** **Dosage Form(s): Tablets** **Strength: 1 g** **Usual Starting Dose:** (b) (4) **2 g orally 3 times daily with meals** **Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)**	**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	Zenapax (Daclizumab) Solution for Injection **Strength:** 5 mg/ mL **Dose:** **Kidney transplant rejection prophylaxis:** 1 mg/kg intravenously, followed by 4 more doses of 1 mg/kg intravenously once every 2 weeks.	**Orthographic:** The letter strings 'Zere' in Zerenex and 'Zena' in Zenapax can look similar when scripted. The ending letter pairs 'ex' and 'ax' look similar when scripted. **Phonetic:** Both names have three syllables with similar sounding first syllable. The letter pair 'ex' in Zerenex and 'ax' in Zenapax sounds similar. **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage:** There is numerical similarity between Zenapax 100 mg and Zerenex 1 g or Zerenex 1000 mg. **Dosage form:** Both products are only available in a single dosage form which can be omitted from a prescription. **Route of administration:** The route can be omitted since Zenapax is only administered intravenously and Zerenex is administered orally.	**Orthographic:** The down stroke letter 'p' in Zenapax looks different from the letter 'n' in Zerenex **Phonetic:** The letter string 'ren' in Zerenex and 'nap' in Zenapax sound different **Frequency of administration:** Once every 2 weeks vs. three times daily.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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	Zervalx (L-Methylfolate) Tablet **Strength:** 7.5 mg **Dose:** 7.5 mg to 15 mg orally once daily	**Orthographic:** Both names start with the letter string 'Zer'. The letter pair 'lx' in Zervalx and 'ex' in Zerenex can look similar when scripted. **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Dosage/dosage form:** Both can be prescribed as '1 tablet'. **Route of administration:** Both products are administered orally.	**Orthographic:** The letter pair 'en' in Zerenex looks different when scripted from 'va' in Zervalx. **Frequency of administration:** Once daily vs. three times daily.

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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)		

Refer

No.	Proposed name: Zerenex (Ferric Citrate Coordination Complex) Dosage Form(s): Tablets Strength: 1 g Usual Starting Dose: (b) (4) 2 g orally 3 times daily with meals Dose Adjustment: Increase or decrease by 1 g to 2 g per day at 2 to 4 weeks intervals as needed (max 12 g daily)	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	Xerese (Acyclovir and Hydrocortisone) Topical Cream **Strength:** 5%-1% **Dose:** Apply five times daily for 5 days.	**Orthographic:** The letter strings 'Zerene' and 'Xerese' look similar when scripted. **Strength:** Both products are single strength, and therefore can be omitted from the prescription. **Route of administration:** The route can be omitted since Xerese is only administered topically and Zerenex is administered orally.	**Orthographic:** The extra letter 'x' at the end of Zerenex lengthens the suffix providing the only orthographic differentiation between both names. **Dosage:** 'Apply five times daily' or 'as directed' for Xerese vs. 1 TID for Zerenex

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/s/

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02/07/2014

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02/07/2014

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:	October 25, 2013
Reviewer:	Kimberly DeFronzo, RPh, MS, MBA Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	(b) (4) (Ferric Citrate) Tablets, 1 g
Application Type/Number:	NDA 205874
Applicant/Sponsor:	Keryx Biopharmaceuticals, Inc.
OSE RCM #:	2013-1919

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/s/

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