CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204399Orig1s000

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:	July 11, 2013
Reviewer:	Manizheh Siahpoushan, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	James Schlick, RPh, MBA Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Vogelxo (Testosterone) Gel 50 mg of Testosterone per 5 gram Gel
Application Type/Number:	NDA 204399
Applicant/Sponsor:	Upsher-Smith Laboratories Inc.
OSE RCM #:	2013-1080

*** 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, Vogelxo, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Upsher-Smith Laboratories submitted a 505 (b)(2) application for NDA 204399 on October 18, 2012. Vogelxo is the third proposed proprietary name submitted for this product. The previous names, [redacted] and [redacted] were found unacceptable (see OSE Review #2013-325 and #2013-712).

1.2 PRODUCT INFORMATION

The following product information is provided in the May 3, 2013 proprietary name submission.

- Active Ingredient: Testosterone
- Indication of Use: Testosterone replacement therapy in adult males for the treatment of primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired)
- Route of Administration: Topical
- Dosage Form: Gel
- Strength: 50 mg of testosterone per tube/packet or 12.5 mg of testosterone per pump actuation
- Dose and Frequency: The starting dose is 50 mg of testosterone (one tube or packet or 4 pump actuations) applied topically once daily preferably in the morning to clean, dry, intact skin of the shoulders and/or upper arms. Dose may be increased to 100 mg of testosterone (two tubes/packets or 8 pump actuations)
- How Supplied:
    - Unit-dose tubes in cartons of 30 and unit-dose packets in cartons of 30. Each tube or packet contains 50 mg of testosterone in 5 gram of gel
    - Metered-dose pump is supplied in cartons of 2. Each pump delivers 12.5 mg of testosterone per complete pump actuation. Each pump actuation delivers 1.25 gram of gel. Each metered-dose pump contains 75 gram of gel and can dispense 60 doses.
- Storage: Controlled Room Temperature
- Container and Closure System:
    - Tube: The package presentation is a printed 3" x 5" [redacted] blind-end tube with a removable orifice seal and white ribbed screw cap and filled with 5 gram of drug product, and then the open end is crimped and sealed under [redacted].

- Packet: Consists of printed [redacted] (b) (4) foil. The product contact layer of the foil is composed of [redacted] (b) (4). The packet contains 5 grams of drug product and [redacted] (b) (4) sealed.

Pump: Consists of a multiple dose 100 mL pouch contained within a bottle sealed with a metering pump. Each pump dispenses 1.25 gram of product when the pump mechanism is fully depressed once. The pump contains 60 metered actuations. [redacted] (b) (4)

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 Reproductive and Urologic Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

The May 7, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Vogelxo, is not derived from any one particular concept. This proprietary name is comprised of a single word. Vogelxo contains 'gel' in the name. This product is a gel. Incorporation of a dosage form into a name is generally discouraged because it may limit the use of the same proprietary name or render it misleading if a different dosage form of the product is developed in the future. However, in this case, 'gel' is in the infix of the name and does not readily convey the finished dosage form. Therefore, it is unlikely to impact future use of the name should a different dosage form be developed. Additionally, we have identified a currently marketed product with 'gel' in the infix of the name that is not a gel dosage form (i.e., Angeliq).

2.2.3 FDA Name Simulation Studies

Forty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products, nor did they appear or sound similar to a currently marketed U.S. product or product in the pipeline. Eighteen out of forty-three prescription study participants (five outpatient and thirteen inpatient) interpreted the name correctly as 'Vogelxo'. Eleven outpatient prescription study participants interpreted the name as 'Vagelxo'. Twelve voice prescription study

participants misinterpreted the name as the following: Vogelso, Vojypsul, Volgel, Volgelfil, Volgelsil, Volgelso, Volgeltso (#2), Volgeltzo, Volgelzo, Voljelso, and Voljeltso. We considered all the misinterpretations by the participants from the inpatient, outpatient, and voice prescription studies in our orthographic and phonetic evaluation of the proposed proprietary name, Vogelxo (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, May 15, 2013 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not have any promotional or safety concerns relating to the proposed name at the initial phase of the proprietary name review. However, they stated that the proposed name, Vogelxo, is difficult to pronounce. The Applicant's intended pronunciation of the proposed proprietary name is voh-JELKS-oh. DMEPA considered the Applicant's intended pronunciation as well as a variety of pronunciations that could occur in the English language or as a result of difficulties in pronouncing the name (e.g., Volgelxo, Volgelzo, Volgeltso, Vogelso, Vogelzo, etc.). We compared the intended pronunciation of Vogelxo, as well as all the other possible pronunciations of this name with the pronunciation of other drug names and could not find similarity to another name.

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,Vogelxo. Table 1 lists the names with potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Vogelxo identified by the primary reviewer (PR), the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by (b) (4)

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)

Look Similar					
VoSol	(b) (4)	Vagilia	PR	Regitine	EPD
Vagifem	EPD	Negaban	EPD	Rosadan	EPD
Reyataz	EPD	Rezulin	EPD	Vasolex	EPD
Nogenic	EPD	Visicol	EPD	Vicoclear	EPD
Vogelmistel	EPD	Rapaflo	EPD	Voltaren	EPD
Vepsid	EPD	Vigamox	EPD	Vigorex	EPD
Legatrin	EPD	Vogalib	EPD	Vasotec	EPD
Nasaflo Neti Pot	EPD	Vagisil	EPD	Xofigo	PR

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Xarelto	PR	Lofibra	PR	Moxduo	PR
Refissa	PR	Reglan	PR	Repliva	PR
Rogaine	PR	Yodoxin	PR	Lazanda	PR
Lexapro	PR				
Look and Sound Similar					
Viagra	(b) (4)				

Our analysis of the 35 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the 35 names will pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on May 23, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Reproductive and Urologic Products on May 24, 2013, they stated no additional concerns with the proposed proprietary name, Vogelxo.

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 Marcus Cato, OSE project manager, at 301-796-3903.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Vogelxo, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your May 3, 2013 submission are altered, the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

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. [1]

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

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

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

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

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

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

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Vogelxo	**Scripted May Appear as**	**Spoken May Be Interpreted as**
Capital 'V'	R, U, N, Y, W, L, X	
Lower case 'v'	r, u, w, n, x	D, f, p, ph, t, vv
Lower case 'o'	a, c, e, u, l, s	Oh
Lower case 'g'	q, j, s, y	K, j
Lower case 'e'	c, i, a, l, o, u, p	Any vowel
Lower case 'l'	b, l, t, P, A, c, e, s	
Lower case 'x'	n, z, v, t, y, a, d, f, k, p	Ex, ks, kz, s, z
Letter strings		
Vo	mi, w	Vol
El	d, a, ei, cl, dc, ll, il	al, il
Xo	W	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Vogelxo Study (Conducted on 5/17/13)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Vogelxo Apply 2 tubes topically daily	Vogelxo Apply 4 pumps daily #1
Outpatient Prescription: Vogelxo Apply 4 pumps daily #1 pump	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

190 People Received Study
43 People Responded

Study Name: Vogelxo

Total	17	12	14	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
VAGELXO	11	0	0	11
VAYELXO	1	0	0	1
VOGELSO	0	1	0	1
VOGELXO	5	0	13	18
VOGELXRE	0	0	1	1
VOJYPSUL	0	1	0	1
VOLGEL	0	1	0	1
VOLGELFIL	0	1	0	1
VOLGELSIL	0	1	0	1
VOLGELSO	0	1	0	1
VOLGELTSO	0	2	0	2
VOLGELTZO	0	1	0	1
VOLGELZO	0	1	0	1
VOLJELSO	0	1	0	1
VOLJELTSO	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 Vogelxo	Failure preventions
1.	Vosol	Acetic Acid	Look	The name pair has sufficient orthographic differences.
2.	Vagilia	Sulfabenzamide, Sulfacetamide, Sulfathiazole	Look	This product and the product name are discontinued and not currently marketed. The product name appears as 'discontinued' on the Facts & Comparisons, Drugs & FDA, Orange Book, and Red Book online databases, as well as a 'Dead' status on USPTO. Additionally, the name Vagilia has not been utilized in practice.
3.	Vicoclear DH	Hdrocodone Bitartrate, Guaifenesin	Look	The name pair has sufficient orthographic differences.
4.	Voltaren	Diclofenac Sodium	Look	The name pair has sufficient orthographic differences.
5.	Vepesid	Etoposide	Look	The name pair has sufficient orthographic differences.
6.	Visicol	Sodium Phosphate, Dibasic, Sodium Phosphate, Monobasic	Look	The name pair has sufficient orthographic differences.
7.	Nasaflo Neti Pot	Sodium Bicarbonate and Sodium Chloride	Look	The name pair has sufficient orthographic differences.
8.	Viagra	Sildenafil Citrate	Look and Sound	The name pair has sufficient orthographic and phonetic differences.
9.	Lofibra	Fenofibrate	Look	The name pair has sufficient orthographic differences.
10.	Xofigo	Radium RA 223 Dichloride	Look	The name pair has sufficient orthographic differences.
11.	Yodoxin	Iodoquinol	Look	The name pair has sufficient orthographic differences.

No.	Proprietary Name	Active Ingredient	Similarity to Vogelxo	Failure preventions
12.	Lazanda	Fentanyl	Look	The name pair has sufficient orthographic differences.
13.	Vogelmistel	European Misteltoe	Look	The name pair has sufficient orthographic differences. The name was identified in the Natural Medicine database. It is a homeopathic remedy used for cancer, reducing side effects of chemotherapy and radiation therapy. The name has not been used in practice.
14.	Refissa	Tretinoin	Look	The name pair has sufficient orthographic differences.
15.	Rezulin	Troglitazone	Look	The name is discontinued with no generic equivalents currently available in the market. The Application for this product was withdrawn by the Federal Register on January 10, 2003 for safety reasons. Additionally, the name pair has sufficient orthographic differences.
16.	Nogenic	N/A	Look	Name identified in the Red Book database with a "Deactivated" status (included the repackagers search criteria). The active ingredient is listed as 'cleanser and moisturizer'. No other product characteristics could be found in any of the available pharmaceutical databases. Additionally, the name pair has sufficient orthographic differences.
17.	Vigamox	Moxifloxacin Hydrochloride)	Look	The name pair has sufficient orthographic differences.

No.	Proprietary Name	Active Ingredient	Similarity to Vogelxo	Failure preventions
18.	Vigorex	Avena Sativa	Look	A homeopathic preparation identified in the Natural Medicines database (Vigorex Femme and Vigorex Forte). According to the editor's comments in this database, the product has been discontinued by the manufacturer. Additionally, the name pair has sufficient orthographic differences.
19.	Vogalib	N/A	Look	Name identified in the Micromedex database, as a product name in France. No other information could be obtained from any of the available pharmaceutical databases regarding this product name. Additionally, the name pair has sufficient orthographic differences.
20.	Vagisil	N/A	Look	Name identified in the Red Book online database. Two products, Vagisil Deodorant Powder or Vagisil Feminine Moisturizer are non prescription products listed under Vagisil in this database; however no product characteristics could be found in any of the available pharmaceutical databases. The name, Vagisil has not been utilized in practice. Additionally, the name pair has sufficient orthographic differences.
21.	Negaban	N/A	Look	Name identified in the Micromedex database as a product name in Netherlands and Belgium. No product characteristics could be obtained from any of the available pharmaceutical databases. Additionally, the name pair has sufficient orthographic differences.
22.	Lexapro	Escitalopram	Look	The name pair has sufficient orthographic differences.

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.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength:** **50 mg of Testosterone per 5 gram of gel** **Usual Dose:** **50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Vagifem (Estradiol) Vaginal Tablets 10 mcg and 25 mcg Usual Dose: Insert one tablet vaginally once daily for 2 weeks.	Orthographic: Both names share the same shape and length (seven letters), the beginning letter 'V' followed by similar scripted letters 'o' vs. 'e', third position downstroke 'g' followed by similar scripted letter strings in the same position of each name '-el-' vs. '-if-'. Frequency of Administration: Once daily Possible Partial Overlap in the Usual Dose: One tube may be misinterpreted as one tab or vise versa.	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-em' in Vagifem when scripted and can help differentiate Vogelxo and Vagifem when scripted. Strength: Single strength (50 mg of testosterone per 5 grams of gel) vs. multiple strengths (10 mcg and 25 mcg) with no overlap between the strengths.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Rosadan (Metronidazole) Cream, 0.75% Gel, 0.75% Usual Dose: Apply a thin film to the affected area(s) twice daily (or apply as directed).	Orthographic: Both names consist of seven letters, share similar scripted beginning letter strings 'voge-' vs. 'Rosa-' followed by an upstroke. Route of Administration: Topical Overlap in the Dosage Form: Gel Strength: Single strength Partial Overlap in the Usual Dose: Both products may be prescribed as 'apply as directed'	Orthographic: The letter string '-elxo' in Vogelxo does not appear similar to the letter string '-adan' when scripted and can help differentiate Vogelxo and Rosadan when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Regitine (Phentolamine Mesylate) Injection, 5 mg Usual Dose: For pheochromocytoma diagnosis: Adults: 5 mg intravenously at least 24 hours before the test Children: 0.05 mg/kg/dose to 0.1 mg/kg/dose intravenously.	Orthographic: Both names share similar scripted beginning letter strings 'Vo-' vs. 'Re-', a third position downstroke 'g' followed by similar scripted letter strings in the same position of each name '-el-' vs. '-it-'. Strength: Single strength Partial Overlap in the Frequency of Administration: Once	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-ine' in Regitine and can help differentiate Vogelxo and Regitine when scripted. Usual Dose: One tube, one packet, 4 pumps (or 50 mg) or two tubes, two packets, 8 pumps (or 100 mg) vs. 5 mg or weight based dosing with no overlap between the doses.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Reyataz (Atazanavir Sulfate) Capsules 100 mg, 150 mg, 200 mg, and 300 mg Usual Dose: Adults and adolescents (weighing 40 kg or more): 300 mg orally plus Ritonavir (100 mg) once daily. Children less than 40 kg: 200 mg plus Ritonavir orally once daily. Children less than 20 kg: 150 mg plus Ritnonavir orally once daily.	Orthographic: Both names share the same shape (if the ending letter 'z' in Reyataz is not scripted as a downstroke) and length (seven letters) and similar scripted beginning letter strings 'Vogel-' vs. 'Reyat-'. Frequency of Administration: Once daily Possible Overlap in the Usual Dose: 100 mg	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-az' in Reyataz and can help differentiate Vogelxo and Reyataz when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Vasolex (Castor Oil, trypsin, Balsam Peru) Ointement 788 mg/90 usp units/87 mg/gram Usual Dose: Apply to the affected area(s) twice daily (or apply as directed).	Orthographic: Both names consist of seven letters, share the beginning letter 'V' followed by similar scripted letter strings in the same position of each name '-ogel-' vs. '-asol-'. Route of Administration: Topical Strength: Single strength Overlap in the Usual Dose: Both products may be prescribed 'Apply as directed'.	Orthographic: The ending letter string '-xo' does not appear similar to the ending letter string '-ex' in Vasolex and can help differentiate Vogelxo and Vasolex when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Rapaflo (Silodosin) Capsules 4 mg and 8 mg Usual Dose: 4 mg (creatinine clearance of 30 ml/min to 49 ml/min) to 8 mg (or one capsule) orally once daily.	Orthographic: Both names consist of seven letters, share similar scripted beginning letter strings 'Vo-' vs. 'Ra-', a third position downstroke 'g' vs. 'p' followed by similar scripted letter strings in the same position of each name '-el-' vs. '-af-', and the ending letter 'o'. Frequency of Administration: Once daily Possible Partial Overlap in the Usual Dose: 4 or 8 (pumps vs. capsules)	Orthographic: The letter 'x' in Vogelxo does not appear similar to the upstroke 'l' in Rapaflo and provides a different shape for this name. This can help differentiate the name Vogelxo from the name Rapaflo when scripted. Strength: Single strength (50 mg of testosterone per 5 grams of gel) vs. multiple strengths (4 mg and 8 mg).

No.	Vogelxo (Testosterone) Dosage Form: Gel Strength: 50 mg of Testosterone per 5 gram of gel Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Legatrin PM (Diphenhydramine Hydrochloride and Acetaminophen) Tablets 50 mg/500 mg Usual Dose: One tablet orally once daily before bedtime.	Orthographic: Both names share similar scripted beginning letter strings 'Vo-' vs. 'Le-', a third position downstroke 'g' followed by similar scripted letter strings '-elx-' vs. '-atr-'. Strength: Single strength Overlap in the Frequency of Administration: Once daily Possible Partial Overlap in the Usual Dose: One tube may be misinterpreted as one tab or vise versa.	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-rin' in Legatrin PM and can help differentiate Vogelxo and Legatrin when scripted.

No.	Vogelxo (Testosterone) Dosage Form: Gel Strength: 50 mg of Testosterone per 5 gram of gel Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Vasotec (Enalapril Maleate) Tablets, 2.5 mg, 5 mg, 10 mg, 20 mg (Enalaprilat) Solution for Injection 1.25 mg/mL Usual Dose: The usual dosage range is 10 mg to 40 mg orally per day given in one to two divided doses. The intravenous dosage is 0.625 mg to 1.25 mg every six hours for adults. For infants more than one month of age and children: 5 mcg/kg/dose to 10 mcg/kg/dose intravenously every 8 to 24 hours. For neonates: 5 mcg/kg/dose to 10 mcg/kg/dose every 8 to 24 hours.	Orthographic: Both names consist of seven letters, share the beginning letter 'V' followed by similar scripted letter strings in the same position of each name '-ogel-' vs. '-asot-'. Possible Overlap in the Frequency of Administration: Once daily Possible Overlap in the Usual Dose: One tube may be misinterpreted as one tab or vise versa.	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-ec' in Vasotec and can help differentiate Vogelxo and Vasotec when scripted. Strength: Single strength (50 mg of testosterone per 5 gram of gel) vs. multiple strengths (2.5 mg, 5 mg, 10 mg, 20 mg, or 1.25 mg per mL) with no overlap between the strengths.

No.	Vogelxo (Testosterone) Dosage Form: Gel Strength: 50 mg of Testosterone per 5 gram of gel Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Moxduo[***] (Morphine Sulfate and Oxycodone Hydrochloride) Tablets 3 mg/2 mg, 6 mg/4 mg, 9 mg/6 mg, 12 mg/8 mg (Proposed proprietary name (NDA 203077) (b) (4) [redacted] (b) (4) [redacted]	Orthographic: Both names share similar scripted beginning letters 'V' vs. 'M', a second position letter 'o' followed by similar scripted letter strings '-gelx-' vs. '-xdu-', and an ending letter 'o'. Possible Partial Overlap in the Usual Dose: One tube may be misinterpreted as one tab or vise versa.	Strength: Single strength (50 mg testosterone per 5 grams of gel) vs. multiple strengths (3 mg/2 mg, 6 mg/4 mg, 9 mg/6 mg, or 12 mg/8 mg) with no overlap between the strengths.

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

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Reglan (Metoclopramide Hydrochloride) Tablets, 5 mg and 10 mg Solution for Injection 5 mg/mL Usual Dose: Adults: depending on the treatment, 5 mg to 45 mg orally, intravenously, or intramuscularly four times per day, 30 minutes before meals and at bedtime. In children and adolescents dosing is weight based and varies based on the type of treatment.	Orthographic: Both names share similar scripted beginning letter strings 'Vo-' vs. 'Re-', a third position downstroke 'g', and an upstroke 'l' in similar positions of each name (fifth vs. fourth). Possible Partial Overlap in the Usual Dose: 5 or 10 (grams of gel vs. mg) or one tube may be misinterpreted as one tab or vise versa.	Orthographic: The ending letter string '-xo' in Vogelxo does not appear similar to the ending letter string '-an' in Reglan and can help differentiate Vogelxo and Reglan when scripted. Additionally, the extra letter 'e' between the downstroke 'g' and the upstroke 'l' in Vogelxo (vs. no letters between the downstroke 'g' and the upstroke 'l' in Reglan) provides a different shape and a longer length for this name which can also help differentiate Vogelxo and Reglan when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Repliva 21/7 (Multivitamin with Iron) Tablets (According to the Facts and Comparisons database, this product name was discontinued in February 2011; however, generic equivalents are marketed.) Usual Dose: One tablet orally once daily.	Orthographic: Both names consist of seven letters, share similar scripted beginning letters 'Vo-' vs. 'Re-', a third position downstroke 'g' vs. 'p', and similar position upstroke 'l' (fifth vs. fourth position). Strength: Single strength Frequency of Administration: Once daily Possible Partial Overlap in the Usual Dose: One tube may be misinterpreted as one tab or vise versa.	Orthographic: The letter string '-gelxo' in Vogelxo does not appear similar to the letter string '-pliva' and can help differentiate Vogelxo and Repliva when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Rogaine (Minoxidil) Topical Solution 2% and 5% Usual Dose: Apply 1 mL once or twice daily (one or two applications per day or as directed).	Orthographic: Both names consist of seven letters, share similar scripted beginning letters 'V' vs. 'R' followed by the letter string '-og-' and similar scripted vowels 'e' vs. 'a'. Route of Administration: Topical Possible Overlap in the Usual Dose: Both products may be prescribed 'Apply as directed'.	Orthographic: The ending letter string '-elxo' in Vogelxo does not appear similar to the ending letter string '-aine' in Rogaine and can help differentiate Vogelxo and Rogaine when scripted.

No.	**Vogelxo (Testosterone)** **Dosage Form: Gel** **Strength: 50 mg of Testosterone per 5 gram of gel** **Usual Dose: 50 mg of Testosterone or 5 gram of gel (or one tube, one packet, or 4 pump actuations) once daily. Dose may be increased to 100 mg of Testosterone or 10 grams of gel (or two tubes, two packets, or 8 pump actuations) once 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.	Xarelto (Rivaroxaban) Tablets 10 mg, 15 mg, 20 mg Usual Dose: Take 15 mg and 20 mg with food; take 10 mg with or without food. For patients with CrCl greater than 50 mL/min: 20 mg orally once daily with the evening meal. For patients with CrCl of 15 mL/min to 50 mL/min: 15 mg orally once daily with the evening meal.	Orthographic: Both names consist of seven letters, share similar scripted beginning letter strings 'Vo-' vs. 'Xa-', and similar scripted ending letter strings '-elxo' vs. '-elto'. Overlap in the Frequency of Administration: Once daily Possible Partial Overlap in the Usual Dose: 10 (grams of gel vs. mg) or one tube may be misinterpreted as one tab.	Orthographic: The downstroke 'g' in Voglexo provides a different shape for this name and can help differentiate Vogelxo and Xarelto when scripted.

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

/s/

MANIZHEH SIAHPOUSHAN
07/11/2013

JAMES H SCHLICK
07/11/2013

CAROL A HOLQUIST
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