CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125360

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

Date:	July 21, 2010
To:	Russell Katz, MD, Director Division of Neurology Products
Through:	Carlos Mena-Grillasca, RPh, Team Leader Mena 7/21/10 Denise P. Toyer, PharmD, Deputy Director DPToyer 7/21/2010 Division of Medication Error Prevention and Analysis (DMEPA)
From:	Walter Fava, R.Ph., MSEd., Safety Evaluator Walter Fava 7-21-10 Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Xeomin (IncobotulinumtoxinA) for Injection 50 units and 100 units per vial
Application Type/Number:	BLA 125360
Applicant:	Merz Pharmaceuticals, LLC.
OSE RCM #:	2010-910

1 INTRODUCTION

This re-assessment of the proposed proprietary name responds to the anticipated approval of this BLA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Xeomin, acceptable in OSE Review # 2010-111, dated April 5, 2010. The Division of Neurology Products did not have any concerns with the proposed name, Xeomin, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on January 22, 2010.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous proprietary name review. We used the same search criteria previously used in OSE Review #2010-111. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases referenced in Section 4 did not yield any new names thought to look or sound similar to Xeomin and represent a potential source of drug name confusion.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Xeomin, as of July 13, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

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

DMEPA considers this a final review; however, if approval of the BLA is delayed beyond 90 days from the date of this review, the Division of Neurology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE review # 2010-111 dated April 5, 2010; Proprietary Name Review of Xeomin; Walter Fava, Safety Evaluator.

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

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

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

USAN Stems List contains all the recognized USAN stems.

4. ***CDER Proposed Names List***

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
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Date:	April 5, 2010
To:	Russell Katz, MD, Director Division of Neurology Products
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From:	Walter Fava, R.Ph., Safety Evaluator Walter Fava 4-5-10 Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Xeomin (IncobotulinumtoxinA) for Injection 50 units per vial and 100 units per vial
Application Type/Number:	BLA: 125360
Licensee:	Merz Pharmaceuticals
OSE RCM #:	2010-111

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CONTENTS

EXECUTIVE SUMMARY

Xeomin is the proposed proprietary name for IncobotulinumtoxinA for Injection. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Licensee. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Xeomin, acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the BLA.

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

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Merz Pharmaceuticals, Inc. on January 8, 2010, for an assessment of the proposed proprietary name, Xeomin, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Licensee submitted an external study in support of their proposed proprietary name. Merz Pharmaceuticals Inc., also submitted container labels and carton labeling for review, which will be reviewed under separate cover (OSE Review #2009-1705).

1.2 PRODUCT INFORMATION

Xeomin (incobotulinumtoxinA) is a peripherally-acting muscle relaxant indicated for the treatment of cervical dystonia and benign essential blepharospasm. The total dose for cervical dystonia ranges from 120 units to 200 units (b) (4) injected intramuscularly in divided doses in affected muscles for each treatment. The dose, number and location of injection sites should be based on the number and location of muscles involved, severity of dystonia, and response to previous botulinum toxin injections. The total dose for benign essential blepharospasm is no more than (b) (4) per eye per treatment and is usually injected intramuscularly into the medial and lateral orbicularis oculi of the upper lid and the lateral orbicularis oculi of the lower lid. Xeomin is reconstituted with 0.9% sodium chloride for injection preservative free.

Xeomin will be supplied in packages of one (b) (4) vials.

1.3 REGULATORY HISTORY

The Xeomin (incobotulinumtoxinA) BLA is currently under review by the Division of Neurology Products under BLA 125360 with an anticipated action date of May 2, 2010.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, 2.3, and 2.4 identify specific information associated with the methodology for the proposed proprietary name, Xeomin.

2.1 SEARCH CRITERIA

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

To identify drug names that may look similar to Xeomin, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (one, capital letter 'X'), downstrokes (none), cross strokes (one, 'X'), and dotted letters (one, 'i'). Additionally, several letters in Xeomin may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Xeomin.

When searching to identify potential names that may sound similar to Xeomin, the DMEPA staff search for names with similar number of syllables (3), stresses (XE-o-MIN, xe-O-min, or xe-o-MIN), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can be misinterpreted (See Appendix B). The Licensee's intended pronunciation (Zee-O-men) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE SEARCH

Since Xeomin is marketed internationally, DMEPA searched the Adverse Event Reporting System (AERS) database to identify any existing medication errors. The search was conducted on March 14, 2010 using only the tradename 'Xeomin' and the verbatim terms 'Xeom%' and 'Zeom%', with no MedDRA terms in order to capture all reports for Xeomin.

2.3 FDA PRESCRIPTION ANALYSIS STUDIES

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

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

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

Figure 1. Xeomin Study (conducted on January 25, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: Xeomin 50 unit vial - inject 50 units in divided doses	Xeomin 50 unit vial Return to clinic for injection
Outpatient Medication Order: Xeomin 50 unit Vial Return to clinic for injection	

2.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Licensee submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Licensee. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of fourteen names as having some similarity to the name Xeomin. Nine names were thought to look like Xeomin and include Zemuron, Yasmin, Xanax, Neoral, Neosar, Xibrom, Aramine, Tremin, and Xyrem. One name, Zitamin, was thought to sound like Xeomin. The remaining four names, Xeomeen, Zeomic, Ketamine, and Kloromin, were thought to both look and sound similar to Xeomin.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 19, 2010.

3.2 CDER EXPERT PANEL DISCUSSION

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

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of fifty eight practitioners responded in the prescription analysis studies. However, fifty nine responses were evaluated, as one practitioner provided two responses. Thirty three of the resonses (56%) interpreted the name correctly as "Xeomin," with all the correct interpretations occurring in the written studies. The remainder of the written responses misinterpreted the drug name. Three respondents in the inpatient study interpreted the name as 'Klomin'. Fifteen respondents in the verbal study interpreted the beginning letter 'X' as the letters 'V' or 'Z'. One respondent from the voice prescription study indicated that the name sounded like Tenormin. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies. Because Tenormin was identified in the prescription analysis studies, it will be added to the safety evaluator assessment.

3.4 ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE SEARCH

The AERS search identified only one case involving an adverse event. This case did not involve a medication error, thus it will not be discussed further.

3.5 EXTERNAL STUDY

The risk assessment submitted by the Licensee, (b) (4) found the proposed name acceptable. They identified and evaluated a total of sixty six names thought to have some potential for confusion with the name Xeomin: Geodon, Hivid, Zaleplon, Xalatan, Xeloda, Xenaderm, Xenadrine, XenaFex, Xenazine, Xenergy, Xenical, Xeno Detox, (b) (4), Xerac, Xerononi, Xiadafil VIP, Xibrom, Xifaxan, Xodol, Xolair, Xolegel, Xopenex, X-Trozine, Xyrem, Xyzal, Zaditor, Zanaflex, Zantac, Zaroxolyn, Zeaxanthin, Zeaxanthin Plus, Zebeta, Zegerid, Zelnorm, Zemplar, Zemuron, Zenapax, (b) (4), Zenostim, Zeolite, Zestoretic, Zestril, Zetia, Zevalin, Ziac, Ziagen, Ziana, Zinmax, Zinopin Daily, Zithromax, Zmax, Zoamix, Zocor, Zofran, Zolinza, Zometa, Zomig, Zonalon, Zonegran, ZORprin, Zostavax, Zostrix, Zymar, Zymine, Zyprexa, and Zyrem. DMEPA identified Zemuron, Xibrom, and Xyrem during their evaluation. The remaining 63 names were evaluated in Section 3.7 below.

3.6 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

3.6.1 Initial Phase of Review

In a response to the OSE January 22, 2010, e-mail, the Division of Neurology Products (DNP) did not have any objections to the proposed proprietary name, Xeomin.

3.6.2 Midpoint of Review

On March 19, 2010, DMEPA notified the Division of Neurology Products via e-mail that we had no objections to the proposed proprietary name, Xeomin. Per e-mail correspondence from DNP on April 5, 2010, they indicated that they had no objection to the proposed proprietary name, Xeomin.

3.7 SAFETY EVALUATOR RISK ASSESSMENT

During this review the established name was revised to 'IncobotulinumtoxinA'. Although the original submission references the established name as (b) (4), the (b) (4) Agency's request to change the established name to have the stem of a prefix + botulinumtoxinA. In December 2009, the United States Adopted Name council adopted the stem 'inco', making the established name 'incobotulinumtoxinA', which we considered accordingly in our assessment. Independent searches by the primary Safety Evaluator identified two additional names,

Remeron and Renamin, which were thought to look and/or sound similar to Xeomin and represent a potential source of drug name confusion. In addition, a respondent from the FDA Prescription Analysis Studies identified Tenormin as a name that sounded similar to Xeomin. Thus, we identified a total of 80 names for their similarity to the proposed name: 63 identified in the External Study, two identified by the primary safety evaluator, 1 identified in the prescription analysis studies, and 14 identified in section 3.1 above.

4 DISCUSSION

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

4.1 PROMOTIONAL ASSESSMENT

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

4.2 SAFETY ASSESSMENT

Eighty names were identified as a potential source of confusion with the proposed name, Xeomin. DMEPA did not identify any other aspects of the name that could cause a potential source of confusion. Sixty-four of the 80 names were not evaluated further for the following reasons: Sixty-two of the 80 names lacked orthographic and/or phonetic similarity (see Appendix D); the proprietary name, Xeomeen, is the registered trademark for this product in Mexico; and the proprietary name, Zeomic, is an inorganic antibacterial used in resin applications.

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining sixteen names and lead to medication errors. This analysis determined that the name similarity between Xeomin was unlikely to result in medication errors with any of the sixteen products for the reasons presented in Appendices E and F. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Licensee.

5 CONCLUSIONS AND RECOMMENDATIONS

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

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Laurie Kelley, OSE Project Manager, at 301-796-5068.

5.1 COMMENTS TO THE LICENSEE

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

Xeomin will be re-reviewed 90 days prior to the approval of the BLA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

6 REFERENCES

1. Adverse Events Reporting System (AERS)

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufacturers that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential post marketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

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

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

3. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

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

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

6. 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.

7. 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.

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

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

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

Provides information regarding patent and trademarks.

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

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

11. 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.

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

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

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

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

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

List contains all the recognized USAN stems.

15. Red Book Pharmacy's Fundamental Reference

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

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

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

17. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

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

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

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

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

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

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

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

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

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

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

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

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 Upstrokes Down strokes Cross-stokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a

variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

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

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

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

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any

clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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

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

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

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

the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

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

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

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

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

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

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

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Licensee select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Licensee 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 Licensee. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Licensee 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. Licensees have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Licensee 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 Licensees' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Xeomin	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'X',	K, A, H, Y, V, N, R, or D	'z', 's', 'v', or 'g'
lower case 'e'	a, i, o, c, or l	any vowel
lower case 'o'	a, c, e, or u	any vowel
lower case 'm'	c, ci, ce, o, or u	any vowel
lower case 'i'	e, l	any vowel
lower case 'n'	'm', 'r', 'x', or 'ri'	'gn', 'kn', 'pn', or m

Appendix C: FDA Prescription Study Responses.

Inpatient Medication Order	**Voice Prescription**	**Outpatient Medication Order**
Xeomin	Zenomin	Xeomin
Xeomin	Zennomin	Xeremin
Xeomin	Zenomen	Xeomin
Xeomin	Venomin	Xeomin
Klomin	Vinomin	Xeomin
Xeomin	Enomen	Xeomin
Xeomin	Vanomin	Xeomin
Xeomin	Zonomin	Xeomin
Xeomin	Vinomin	Xeomin
Xeomin	Zenomin	Xeomin
Xeomin or Klomin	Vinomin	Xeomin
Xeomin	Zenoman	Deomir
Xeomin	Zenormin	Deremin
Klomin	Vanomen	Xeomin
Xeomin	Denelmin	Seomin
Xeomin	Venomin	Deomin
Xeomin	Venomin	Xeomin
		Xeomin
		Xeomin
		Desmin

		Xeomin
		Xeomin
		Xeomin
		Xeomin

Appendix D: Proprietary names which lack significant phonetic and/or orthographic similarity to Xeomin

Proprietary Name	Similarity to Xeomin	Proprietary Name	Similarity to Xeomin
Geodon	Look and Sound	Zeaxanthin	Look and Sound
Hivid	Look and Sound	Zeaxanthin Plus	Look and Sound
Sonata (Zaleplon)	Look and Sound	Zebeta	Look and Sound
Xalatan	Look and Sound	Zegerid	Look and Sound
Xeloda	Look and Sound	Zelnorm	Look and Sound
Xenaderm	Look and Sound	Zemplar	Look and Sound
Xenadrine	Look and Sound	Zenapax	Look and Sound
XenaFex	Look and Sound	(b) (4)	Look and Sound
Xenazine	Look and Sound	Zenostim	Look and Sound
Xenergy	Look and Sound	Zeolite	Look and Sound
Xenical	Look and Sound	Zestoretic	Look and Sound
Xeno Detox	Look and Sound	Zestril	Look and Sound
(b) (4)	Look and Sound	Zetia	Look and Sound
Xerac	Look and Sound	Zevalin	Look and Sound
Xerononi	Look and Sound	Ziac	Look and Sound
Xiadafil VIP	Look and Sound	Ziagen	Look and Sound
Xibrom	Look and Sound	Ziana	Look and Sound
Xifaxan	Look and Sound	Zyrem	Look and Sound
Xodol	Look and Sound	Zinopin Daily	Look and Sound
Xolair	Look and Sound	Zithromax	Look and Sound
Xolegel	Look and Sound	Zmax	Look and Sound
Xopenex	Look and Sound	Zoamix	Look and Sound
X-Trozine	Look and Sound	Zocor	Look and Sound
Xyrem	Look and Sound	Zofran	Look and Sound
Xyzal	Look and Sound	Zolinza	Look and Sound
Zaditor OTC	Look and Sound	Zometa	Look and Sound
Zanaflex	Look and Sound	Zonalon	Look and Sound
Zantac	Look and Sound	Zonegran	Look and Sound
Zaroxolyn	Look and Sound	Zostavax	Look and Sound

ZORprin	Look and Sound	Zymar	Look and Sound
Zostrix	Look and Sound	Zyprexa	Look and Sound

Appendix E: Proprietary names with orthographic and/or phonetic similarity to Xeomin, but with multiple differentiating product characteristics

Proprietary name with potential for confusion with Xeomin	**Similarity to Xeomin**	**Strength and Dosage form**	**Usual Dose**	**Other differentiating product characteristics (Xeomin vs other product)**
Xeomin **(clostridium botulinum toxin Type A)**	**NA**	**50 units per vial and 100 units per vial powder for injection**	***Cervical dystonia:*** 10 units to 200 units injected in affected muscle ***Benign Essential Blepharospasm:*** 1.25 units to 2.5 units per injection site not to exceed 25 units per eye per treatment	**NA**
Zemuron (rocuronium)	Look	10 mg/mL, 50 mg/mL, and 100 mg/10 mL Solution for Injection	*Muscular relaxation during routine endotracheal intubation:* **Intravenous dose:** 0.45 mg to 0.6 mg/kg *Muscular relaxation during rapid-sequence intubation:* 0.6 mg to 1.2 mg/kg *Neuromuscular blockade during surgery or mechanical ventilation* **Rapid IV Infusion:** 0.6 mg/kg **Continuous Infusion:** 0.01 mg to 0.012 mg/kg/min	**Route of Administration:** Intramuscular vs Intravenous **Frequency of Administration:** Every 3 months vs one time during procedure **Units of Measure:** Units vs milligrams **Preparation:** Reconstitution required vs solution
Tenormin (atenolol)	Sound	25 mg , 50 mg, and 100 mg tablets	50 mg by mouth once a day	**Dosage Form:** Injectable vs tablet **Route of Administration:** Intramuscular vs oral **Frequency of Administration:** Every 3 months vs daily **Units of Measure:** Units vs milligrams
Xanax (alprazolam)	Look	0.25 mg, 0.5 mg, 1 mg, and 2 mg tablets	*Anxiety Disorders:* 0.25 mg to 0.5 mg by mouth three times a day up to a maximum of 4 mg per day *Anxiety and mood symptoms associated with premenstrual syndrome or premenstrual*	**Dosage Form:** Injectable vs tablet **Route of Administration:** Intramuscular vs oral **Frequency of Administration:**

			dysphoric disorder: 0.25 mg three times a day *Short term treatment of insomnia:* 0.25 mg to 0.5 mg by mouth at bedtime	Every 3 months vs one time during procedure **Units of Measure:** Units vs milligrams
Neoral (cyclosporine)	Look	25 mg and 100 mg capsules 100 mg/mL Solution for intravenous injection	15 mg/kg orally or 5 mg to 6 mg/kg intravenously pre-transplant 5 mg to 6 mg/kg intravenously post-transplant until able to tolerate oral dosage of 7 mg/kg/day in divided doses	**Dosage Form:** Injectable only vs capsule or injectable **Route of Administration:** Intramuscular vs Oral or Intravenous **Frequency of Administration:** Every 3 months vs two to three times a day **Dose:** 1.25 units to 200 units vs 25 mg to 500 mg **Units of Measure:** Units vs milligrams or milligrams/mL
Neosar (cyclophosphamide) Discontinued proprietary name but generic equivalents available	Look	100 mg, 200 mg, 500 mg, 1 gram, and 2 gram powder for injection	500 mg to 4000 mg/m^2 administered intravenously (dose is dependent upon disease state, performance status, tolerance, and concomittant therapy)	**Route of Administration:** Intramuscular vs Intravenous **Units of Measure:** Units vs milligrams
Aramine (metaraminol bitartrate) Discontinued proprietary name but generic equivalents available	Look	10 mg/mL solution for injection	*Subcutaneous or Intramuscular Injections:* 2 mg to 10 mg as needed for hypotension *Intravenous Infusions:* 15 mg to 100 mg in 500 mL 0.9% NaCl or D5W as needed for hypotension	**Frequency of Administration:** Every 3 months vs 'prn' for hypotension **Units of Measure:** Units vs milligrams/mL
Ketamine Hydrochloride	Look and Sound	10 mg/mL, 50 mg/mL, and 100 mg/mL solution for injection	*General anesthesia maintenance:* 0.5 mg to 4.5 mg/kg intravenously or intramuscularly	**Frequency of Administration:** Every 3 months vs one time during procedure **Units of Measure:** Units vs milligrams **Dose:** 1.25 units to 200 units vs 10 mg to 375 mg
Kloromin (chlorpheniramine maleate) Discontinued proprietary name but generic equivalents available	Look and Sound	4 mg tablets	One tablet by mouth every 4 to 6 hours as needed	**Dosage Form:** Injectable vs tablet **Route of Administration:** Intramuscular vs Oral **Frequency of Administration:** Every 3 months vs every 4 to 6 hours as needed

				Dose: 1.25 units to 200 units vs one tablet **Units of Measure:** Units vs milligrams
Remeron (mirtazipine)	Look	15 mg, 30 mg, and 45 mg tablets	15 mg to 45 mg by mouth at bedtime	**Dosage Form:** Injectable vs tablet **Route of Administration:** Intramuscular vs Oral **Frequency of Administration:** Every 3 months vs once at bedtime **Units of Measure:** Units vs milligrams
Zinmax (zinc picolinate)	Look and Sound	50 mg capsules	One capsule daily	**Dosage Form:** Injectable vs capsule **Route of Administration:** Intramuscular vs Oral **Frequency of Administration:** Every 3 months vs once a day **Units of Measure:** Units vs milligrams
Zomig (zolmitriptan)	Look and Sound	2.5 mg and 5 mg tablets 2.5 mg and 5 mg orally disintegrating tablets 5 mg/actuation nasal spray	2.5 mg or 5 mg by mouth as a single dose, may repeat within 2 hours if needed, not to exceed 10 mg in 24 hours. 1 spray into one nostril as a single dose, may repeat once in 2 hours if needed, not to exceed 10 mg in 24 hours.	**Dosage Form:** Injectable vs tablets, orally disintegrating tablets or nasal spray **Route of Administration:** Intramuscular vs oral or nasal **Frequency of Administration:** Every 3 months vs one dose or may repeat one time as needed for headache **Units of Measure:** Units vs milligrams or milligrams per actuation

Appendix F: Potentially confusing names to Xeomin which are unlikely to cause medication errors

Failure Mode: **Name Confusion**	**Causes** **(could be multiple)**	**Rationale that minimizes the risk of medication error**
Xeomin (clostridium botulinum toxin Type A) for Injection 50 units and 100 units per vial		**Usual dose:** ***Cervical Dystonia*** **10 units to 200 units injected in affected muscles** ***Benign Essential Blepharospasm*** **1.25 units to 2.5 units per injection site not to exceed 25 units per eye per treatment**
Yasmin (drospirenone and ethinyl estradiol) 3 mg/30 mcg tablet	Orthographic Similarities include: Both names contain six letters and are similar in length when scripted. The first letter of the names, 'X' vs 'Y', may look similar when scripted. Both names end in the letters 'min'. Phonetic similarities include: The last syllable of both names is the same, 'min'.	Despite orthographic and phonetic similarities, the differentiating product characteristics will minimize confusion between this name pair. *Rationale:* Yasmin is an oral contraceptive taken once a day and is predominantly prescribed on an outpatient basis in a retail pharmacy setting. Xeomin is an injectable product administered intramuscularly by healthcare practitioners in a clinic or inpatient setting. Although unlikely, outpatient retail pharmacy orders for Xeomin written, 'Use as Directed', would likely include a strength, '50 units' or '100 units' and the number of vials to dispense. Yasmin outpatient retail pharmacy orders would likely indicate the number of 'packs' to dispense.
Tremin (trihexypenidyl hydrochloride) 2 mg and 5 mg tablets Discontinued proprietary name but generic equivalents are available	Orthographic similarities include: Both names contain six letters and are similar in length when scripted. The first letters of both names, 'X' vs 'T' may appear similar when scripted and both names end in the letters 'min'. Phonetic similarities include: Both names have the letter 'e' in the first syllable and end in 'min'.	Despite orthographic and phonetic similarities, the differentiating product characteristics will minimize confusion between this name pair. *Rationale:* Tremin is an oral tablet taken up to three times a day. Orders for Tremin would include a product strength in milligrams (2 mg or 5 mg) along with a quantity such as 30, 60, or 90 vs orders for Xeomin which would specify either 50 units or 100 units per vial and the number of vials. (b) (4)

		(b) (4) [1]SDI, Vector One: National®, Years 2000-2009, Extracted 03/2010.
Zitamin (Prenatal Vitamin) tablets	Orthographic similarities include: Both names end in the letters 'min'. Phonetic similarities include: Both names contain three syllables and the first letter of both names, 'X' vs 'Z', sound similar when spoken. Additionally, if Zitamin is pronounced with a soft 'i' as in 'Zit', or an 'e' as in 'Zeet', it may sound similar to Xeomin when spoken.	Despite orthographic and phonetic similarities, the differentiating product characteristics will minimize confusion between this name pair. *Rationale:* The beginning letters, 'Xeo' in Xeomin look different from the corresponding letters, 'Zit' in Zitamin when scripted. Zitamin is an oral vitamin tablet taken once a day. Xeomin is an injectable product used in a clinic or hospital setting and is administered by a healthcare practitioner. Although unlikely, verbal order confusion between this name pair would be minimized by the differentiating product characteristics. Zitamin orders would include quantities such as 30, 60, or 90 tablets, whereas Xeomin orders would include a strength of 50 units or 100 units and the number of vials. (b) (4) [1]SDI, Vector One: National®, Years 2000-2009, Extracted 03/2010.
Renamin (Amino Acid) 6.5% Solution (500 mL)	Orthographic similarities include: Both names contain only one upstroke letter in the first position, the second letter of both names is 'e', and both names end in the letters 'min'. Phonetic similarities include: Both names contain three syllables. The last four letters 'omin' in Xeomin may sound like the last four letters, 'amin' in Renamin.	Despite orthographic and phonetic similarities, the differentiating product characteristics will minimize confusion between this name pair. *Rationale:* Orders for Renamin would be written as part of a total parenteral nutrition order, would include instructions for mixing with Dextrose 5%, and would include infusion rates for intravenous administration, which orders for Xeomin would not include. Renamin orders would include the number of milliliters vs orders for Xeomin which would include the number of units

		(50 units or 100 units). Additionally, the beginning portion of both names, 'Xeo' vs 'Rena' sound different when spoken and look different when scripted.
Zymine (triprolidine hydrochloride) 1.25 mg/5 mL oral solution Discontinued proprietary name but generic equivalents are available	Orthographic similarities include: Both names contain six letters and may appear similar in length when scripted. The first letters of both names, 'X' vs 'Z', may look similar when scripted. Both names contain the letters 'min' at the end. Phonetic similarities include: The first letter of both names, 'X' vs 'Z', may sound similar when pronounced. The letters 'Zy' in Zymine may sound like the letters 'Xe' or 'Zia' when pronounced, making it sound similar to the beginning of Xeomin. Both names contain the letters 'min' at the end.	Despite orthographic and phonetic similarities, the differentiating product characteristics will minimize confusion between this name pair. *Rationale:* Zymine is an oral solution that would be ordered by the number of teaspoonsful with a frequency of every 4 to 6 hours as needed. Zymine orders will indicate a quanity of 'bottles' or 'ounces' or 'milliliters'. Xeomin is an injectable product which would be ordered using the strength designations of 50 units per vial or 100 units with the number of vials or just the dose in units. (b) (4)

[1]SDI, Vector One: National®, Years 2000-2009, Extracted 03/2010.