

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER:**

**22-525**

**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: April 23, 2010

To: Russell Katz, M.D., Director  
Division of Neurology Products

Through: Melina Griffis, RPh, Team Leader  
Denise Toyer, Pharm.D., Deputy Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: Irene Z. Chan, Pharm.D., BCPS, Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Namenda XR (Memantine Hydrochloride) 7 mg, 14 mg, 21 mg, and  
28 mg Capsules

Application Type/Number: NDA 022525

Applicant: Forest Laboratories, Inc.

OSE RCM #: 2010-453

**\*\*\* Note: This review contains proprietary and confidential information that should not be released to the public.\*\*\***

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## **1 INTRODUCTION**

This re-assessment of the proprietary name is written in response to a notification that NDA 022525 may be approved within 90 days. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Namenda XR, acceptable in OSE Review #2009-1914, dated December 30, 2009. The Division of Neurology Products did not have any concerns with the proposed name, Namenda XR, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective as noted in OSE Review #2009-1914.

## **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 phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-1914 for the proposed proprietary name, Namenda XR. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the 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 yielded no new names thought to look similar to Namenda XR and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Namenda XR, as of April 12, 2010.

## **3 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Namenda XR, is not vulnerable to name confusion that can 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, Namenda XR, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA 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 #2009-1914 Proprietary Name Review of Namenda XR; Chan, Irene Z.**
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/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.
4. ***Division of Medication Error Prevention and Analysis proprietary name 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.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22525	ORIG-1	FOREST LABORATORIES INC	NAMENDA XR(MEMANTINE HCL)ER CAPSULES

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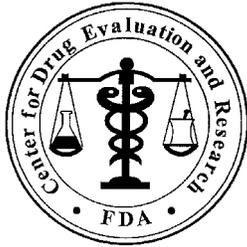
/s/

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

Date: December 30, 2009

To: Russell Katz, M.D., Director  
Division of Neurology Products

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Drug Name(s): Namenda XR (Memantine Hydrochloride) 7 mg, 14 mg, 21 mg, and  
28 mg Capsules

Application Type/Number: NDA 022525

Applicant/Applicant: Forest Laboratories, Inc.

OSE RCM #: 2009-1914

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## **EXECUTIVE SUMMARY**

Namenda XR is the proposed proprietary name for Memantine Hydrochloride Extended Release capsules. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Sponsor. 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 Namenda XR conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

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 Forest Laboratories, Inc. dated October 6, 2009, for an assessment of the proposed proprietary name, Namenda XR, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by [REDACTED] (b) (4) in support of their proposed proprietary name.

The Applicant also submitted draft container labels, carton and insert labeling. The labels and labeling will be reviewed separately under OSE Review #2009-1915.

### **1.2 REGULATORY HISTORY**

Namenda (Memantine Hydrochloride) is currently marketed in the United States. Namenda tablets were approved by the FDA on October 16, 2003 under NDA 021487. Namenda oral solution was approved on April 18, 2005 under NDA 021627. For this application, the Applicant is proposing an extended release formulation of memantine hydrochloride to be marketed under the proprietary name Namenda XR.

### **1.3 PRODUCT INFORMATION**

Namenda XR is indicated for the treatment of moderate to severe dementia of the Alzheimer's type. The recommended initial dose is 7 mg once daily and the maintenance dose is 28 mg once daily. A minimum of one week of treatment with the previous dose should be observed before increasing the dose. Namenda XR will be available in four strengths: 7 mg, 14 mg, 21 mg, and 28 mg. All four strengths will be marketed in bottles of 30 capsules. In addition, the 14 mg and 28 mg capsules will also be available in bottles of 90 capsules. A 4 week titration pack will also be marketed which will include a one week supply of 7 mg, 14 mg, 21 mg and 28 mg tablets.

Namenda (Memantine Hydrochloride) immediate release tablets and oral solution are already approved for the treatment of moderate to severe dementia of the Alzheimer's type. Immediate release Namenda is available as 5 mg and 10 mg tablets, a titration pack, and oral solution in a 2 mg/mL concentration. The recommended initial dose is 5 mg once daily. The recommended target dose is 10 mg twice a day (20 mg per day). The minimum recommended interval between dose increases is one week.

## 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 reviewing the proposed proprietary name, Namenda XR.

### 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter “N” 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.<sup>1,2</sup> Additionally, since omission of a modifier is cited in the literature as a common cause of medication errors<sup>3</sup>, DMEPA considers “Namenda XR” as a complete name as well as “Namenda,” the root term, omitting the modifying term “XR.”

DMEPA staff evaluates the appropriateness of the modifier “XR” for this product in addition to searching commonly used databases (see Section 6) for currently marketed product names that include “XR” and defining the meaning of “XR” for those products.

To identify drug names that may look similar to Namenda XR, 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 root name (7 letters), upstrokes (2, capital letter “N” and lower case letter “d”), downstrokes (none), cross strokes (none), dotted letters (none) and modifiers (XR). Additionally, several letters in Namenda XR may be vulnerable to ambiguity when scripted (see Appendix B). DMEPA staff also considers how the exclusion of “XR” may change the appearance of the name. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Namenda XR.

When searching to identify potential names that may sound similar to Namenda XR, the DMEPA staff search for names with similar number of syllables (three), stresses (NUH-men-dah Eks-Are, nuh-MEN-dah Eks-Are, and nuh-men-DAH Eks-Are), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Sponsor’s intended pronunciation (Nuh-men-dah Eks-Are) was also taken into consideration, as it was included in the Proprietary Name Review Request. Furthermore, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered. DMEPA staff also considers how the exclusion of “XR” may change the sound of the name.

### 2.2 FDA ADVERSE EVENT REPORTING SYSTEM (AERS)

Since the root name “Namenda” has been marketed since 2003, DMEPA conducted a search of the FDA Adverse Event Reporting System (AERS) database to determine if there are any medication errors which may be indicative of potential name confusion with Namenda XR. DMEPA conducted an AERS search on November 10, 2009, for medication errors involving Namenda or memantine hydrochloride.

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

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. *Artificial Intelligence in Medicine* (2005)

<sup>3</sup> Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

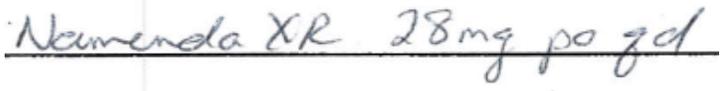
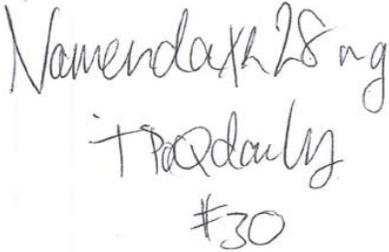
The MedRA High Level Group Terms (HLGT) “Medication Errors” and “Product Quality Issues” were used as search criteria for *Reactions*. The search criteria used for *Products* were active ingredients “memantine” and “memantine hydrochloride,” trade name “Namenda” and verbatim substance search “memantine%” and “namenda%.” No date limitations were set.

The reports were manually reviewed to determine if a medication error occurred. Duplicate reports were combined into cases. The cases that described a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors. If a root cause was associated with name confusion or look and/or sound alike to Namenda, the case was considered pertinent to this review. Those reports that did not describe a medication error or did not describe an error applicable to this review (e.g. errors related to accidental exposures, intentional overdoses, etc.) were excluded from further analysis.

### 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 and verbal prescription was communicated during the FDA prescription studies.

**Figure 1. Namenda XR Study (conducted on October 22, 2009)**

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	<p>Namenda XR 28 mg Dispense #30 1 capsule PO daily</p>
<p><u>Outpatient Prescription:</u></p> 	

### 2.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Sponsor 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 Sponsor. 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 12 names having some similarity to the name Namenda XR; however, one name identified was the proposed name Namenda XR and was not further evaluated. Another name identified was Namenda Titration Pak which is not actually the approved proprietary name. The "Titration Pak" refers to a packaging configuration for Namenda that is currently available on the market. Therefore, DMEPA evaluated the remaining 10 names.

Seven of the names were thought to look like Namenda XR. These include Avandamet, Menactra, (b) (4)\*\*\*, Raniclor, Remicade, Renvela\*\*\*, and Xanax XR.

Three names were thought to both look and sound like Namenda XR. These names are Emend, Namenda, and Neumega.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 19, 2009.

#### **3.2 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 Namenda XR.

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

#### **3.3 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE**

The AERS search conducted on November 10, 2009, yielded 89 cases. Of these cases, 84 were excluded from further evaluation for the following reasons. These cases were not related to name confusion with Namenda and will be considered in our review of the product labels and labeling.

- Report of an adverse drug reaction (n=20)
- Report of an accidental exposure (n=2)
- Product quality complaint that is beyond the scope of this review (n=1)
- Drug monitoring error not relevant to this review (n=1)
- Wrong patient error where one patient received another patient's medicine (n=2)
- Improper dose errors, including accidental and intentional overdoses (n=57)
- Report of a potential error that did not reach the patient and is not relevant to this review (n=1)

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

The 5 remaining cases were wrong drug errors between Namenda and another product:

- In one case, a pharmacy student was asked by physicians for “information about the new drug to treat Alzheimer’s disease – Amantadine.” The intended drug request was for memantine (established name for Namenda). This error occurred in 2004, less than one year after FDA approval of Namenda. No contributing factors were reported.
- One case involved a patient who was admitted to the hospital on memantine; however, upon discharge, the patient’s memantine was not reordered. Instead, this patient was ordered amantadine in error upon discharge. This error was later discovered at the patient’s nursing home and the amantadine was discontinued. The report noted that “memantine...may have been mistaken for amantadine by the physician at admission.”
- One case involved name confusion between “memantine” and “amatine.” The provider intended to write for “memantine” but instead wrote a prescription for “amatine,” which is the Canadian name for midodrine. The only contributing factor noted was “medication name that is not used in the US.”
- One case involved a dispensing error. The intended medication was a prenatal vitamin but it was accidentally filled instead with Namenda. There were no contributing factors noted in this report.
- In one case, a prescription for memantine (Namenda) was filled with sibutramine (Meridia). No contributing factors were noted in this report.

### **3.4 FDA PRESCRIPTION ANALYSIS STUDIES**

A total of 23 practitioners responded in the prescription analysis studies but none of the responses overlapped with any existing or proposed drug names. Fourteen of the participants interpreted the name correctly as “Namenda XR.” The remainder of the responses (n=9) misinterpreted the drug name. Several misinterpretations occurred with the “XR” misinterpreted as “XL.” See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### **3.5 EXTERNAL STUDY**

In the proposed name risk assessment submitted by the Applicant, (b)(4) identified and evaluated a total of 13 drug names thought to have some potential for confusion with the name Namenda XR: Augmentin XR, D-Amine-SR, Demadex, Effexor XR, Focalin XR, Mentax, Namenda, Nelfinavir, Nexavar, Nexium, Tegretol XR, Zymine DXR and Zymine XR. Of the names identified by (b)(4) one was also identified by DMEPA during the database searches: Namenda. The remaining 12 names will be considered in the safety evaluator assessment.

### **3.6 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)**

#### ***3.6.1 Initial Phase of Review***

In a response to the OSE October 20, 2009 e-mail, the Division of Neurology Products (DNP) did not object to the proposed proprietary name, Namenda XR.

#### ***3.6.2 Midpoint of Review***

On November 13, 2009, DMEPA notified the Division of Neurology Products (DNP) via e-mail that we had no objections to the proposed proprietary name Namenda XR. Per e-mail correspondence from the

Division of Neurology Products on November 23, 2009, they indicated that they concur with our assessment of the proposed proprietary name, Namenda XR.

### **3.7 SAFETY EVALUATOR RISK ASSESSMENT OF PROPOSED PROPRIETARY NAME**

Independent searches by the primary Safety Evaluator resulted in the identification of 20 additional names which were thought to look or sound similar to Namenda XR and represent a potential source of drug name confusion.

The names identified by the primary Safety Evaluator to have look-alike similarities are Avandia XR, Hamamelis, (b) (4), Humulin BR, Humulin R, Momentum, Neurodex, Neurontin, Nexcede, Nicomide, (b) (4), Normalex, Novastan, (b) (4), Rescula, Revatio, Revonto, Sermorelin, (b) (4), and Sinusalia.

Thus, we evaluated a total of 42 names for their similarity to the proposed name: 12 identified in the External Study, 20 identified by the primary safety evaluator and 10 identified in section 3.1 above.

The searches also confirmed that the modifier “XR” is commonly used to identify extended release formulations (e.g. Effexor XR, Augmentin XR, Xanax XR).

## **4 DISCUSSION**

DMEPA’s evaluation considered “Namenda XR” as a complete name as well as “Namenda,” the root term with omission of the modifying term “XR” because omission of a modifier is cited in literature as a common cause of medication error. Post-marketing experience has shown that the introduction of product line extensions result in medication errors if the modifier is omitted and product characteristics are similar or overlap. In this case, sufficient product characteristic differences minimize the likelihood of medication error between Namenda XR and Namenda (see Appendix K).

A search of the FDA AERS database was conducted and identified five cases of wrong drug errors between Namenda and other products. In four of the five cases, no contributing factors were noted; therefore, we are unable to determine if name confusion caused these errors. Considering that Namenda has been on the market over six years and there is no well-defined risk of name confusion between this product and other proprietary names in the marketplace, DMEPA does not believe the introduction of the extended release formulation (Namenda XR) will exacerbate name confusion medication errors.

### **4.1 NAMENDA XR**

Neither DDMAC nor the Division of Neurology Products had concerns with the proposed name Namenda XR. DMEPA did not identify other factors besides names with potential similarity to Namenda XR that would render the name unacceptable.

In total, 42 names were identified and evaluated by DMEPA. Twenty-four of the 42 names were not evaluated further for the following reasons: 14 of the 42 names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Namenda XR (see Appendices D and E), ten other names did not undergo failure mode and effect analysis (FMEA) because they were either herbal products not dispensed pursuant to a prescription, products withdrawn or not marketed in the U.S, or proposed proprietary names for products later approved under a different proprietary name or with no proprietary name (see Appendices F, G, and H).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 18 names and lead to medication errors. This analysis determined that the name similarity between Namenda XR was unlikely to result in medication errors with any of the 18 products for the reasons presented in Appendices I through J. This finding was

consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

## 4.2 MODIFIER XR

Namenda XR will be added to an existing product line that already has two oral dosage formulations (tablets and oral solution). The Applicant proposes to use the root name Namenda and the modifier XR to differentiate the extended-release formulation from the currently marketed products. This naming convention is commonly used when an extended-release dosage form is added to a product line with an existing immediate-release formulation.

In this case, Namenda XR will be dosed once daily, unlike the immediate release product, Namenda, which is dosed twice daily. There are several other products currently marketed where the modifier “XR” corresponds to an extended release product that is dosed once daily. Examples include Xanax XR, Focalin XR, or Effexor XR.

Since, the modifier “XR” adequately emphasizes the most notable difference between Namenda XR and the existing Namenda product, which is the dosing interval, and the modifier XR is a well established and well recognized modifier, DMEPA believes that the modifier “XR” is appropriate for this product.

## 5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Namenda XR, is not promotional nor is it vulnerable to name confusion that can lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Namenda XR, for this product at this time. Our analysis is consistent with the external risk assessment conducted by <sup>(b) (4)</sup> that was provided by the Applicant. The Applicant will be notified via letter.

### 5.1 COMMENTS TO THE SPONSOR

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

The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

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.

## 6 REFERENCES

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

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

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

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

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

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

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in review divisions.

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))

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

10. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at***  
([www.thomson-thomson.com](http://www.thomson-thomson.com))

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

11. ***Natural Medicines Comprehensive Databases*** ([www.naturaldatabase.com](http://www.naturaldatabase.com))

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

12. ***Stat!Ref*** ([www.statref.com](http://www.statref.com))

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

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

USAN Stems List contains all the recognized USAN stems.

**14. Red Book Pharmacy's Fundamental Reference**

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

**15. Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

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

**16. Medical Abbreviations Book**

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

## **APPENDICES**

### **Appendix A:**

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>4</sup>

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.<sup>5</sup> 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

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<sup>4</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>5</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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.<sup>6</sup> 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 because similarly 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 Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant 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-	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

<sup>6</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

alike		Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	
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	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

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 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.<sup>7</sup> 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.

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<sup>7</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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 possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant 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 Applicant 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. 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 Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants’ 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

<b>Letters in name, Namenda</b>	<b>Scripted may appear as</b>	<b>Spoken may be interpreted as</b>
Capital ‘N’	M, R, U, h	M
lower case ‘n’	a, h, m, r, s, or u	m
lower case ‘a’	c, ci, ce, ic, ir, o, or u	any vowel
lower case ‘m’	n, ni, r, s, u, v or x	n
lower case ‘e’	A, g, or n	any vowel
lower case ‘n’	a, h, m, r, s, or u	m
lower case ‘d’	ci, cl	t
lower case ‘a’	c, ci, ce, e, o, ic, ir, o, r, s, u, or x	any vowel

**Appendix C:** FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Namenda XR	Namenda XR	Nomenda XR
Namenda XR	Namendaxl	namenda xr
Kamenda xr	Namenda XL	
Namenda XR	Namenda XR	
Namenda XR	Nameinda XR	
Namenda XR	Namenda XR	
	Namenda XL	
	Namendaxr	
	Namenda XR	
	Namendaxa	
	Namenda XR	
	Namendaxe	
	Namenda XL	
	Namenda XR	
	Namenda XR	

**Appendix D:** Drug names that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Namenda XR
Avandamet	Look alike
D-Amine-SR	(b) (4)
Demadex	(b) (4)
Emend	Look alike and sound alike
Mentax	(b) (4)

Nelfinavir	Sound alike
Nexium	Look alike
Zymine DXR	(b) (4)

**Appendix E:** Drug names containing the modifier “XR” that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Namenda XR
Augmentin XR	(b) (4)
Effexor XR	phonetic
Focalin XR	orthographic and phonetic
Tegretol XR	phonetic
Xanax XR	orthographic
Zymine XR	(b) (4)

**Appendix F:** Herbal Product (not dispensed pursuant to a prescription)

Name	Similarity to Namenda XR	Use	Product Description
Hamamelis (leaf and bark of hamamelis virginiana)	Look alike	Possibly effective for hemorrhoids, minor bleeding, and skin irritation. Other uses do not have sufficient reliable information.	The applicable parts of witch hazel are the leaf and bark. The active constituents include gallotannins, gallic acid, myricetin, quercetin, kaempferol, and catechol derivatives. Witch hazel leaf and bark possess astringent, styptic, and anti-inflammatory properties. The leaf contains 8-10% tannins. The bark contains up to 12% tannins.

**Appendix G:** Names withdrawn from the market without therapeutic equivalents available

Proprietary Name	Similarity to Namenda XR	Status and Date
Humulin BR (insulin recombinant human)	Look alike	Product withdrawn by commissioner on March 13, 2009. Applicant requested withdrawal. Drug is no longer marketed in U.S.
Normalex (senna and prune powder extract)	Look alike	OTC product previously marketed; Last lot manufactured in June 2005 and discontinued from the market in August 2005.
Sermorelin (established name for Geref)	Look alike	This product was withdrawn by the Applicant. The effective date of withdrawal was 6/18/09.

**Appendix H:** Unapproved proprietary names<sup>\*\*\*</sup>

Proprietary Name	Similarity to Namenda XR	Status and Date
(b) (4)		
Novastan <sup>***</sup> (argatroban)	Look alike	This name was rejected in OSE Review # 99-103 dated January 5, 2000. This product is currently approved without a proprietary name.

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

Proprietary Name	Similarity to Namenda XR	Status and Date
(b) (4)		

**Appendix I:** Potentially confusing products with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Namenda XR	Strength	Usual Dosage & Administration	Differentiating Product Characteristics (Namenda XR vs. Product)
Namenda XR (memantine hydrochloride)	N/A	7 mg, 14 mg, 21 mg, 28 mg	28 mg once daily	N/A
Humulin R (insulin recombinant human) injectable	Look alike	100 units/mL; 500 units/mL	Individualized dosage injected subcutaneously depending on insulin requirements	<u>Route of Administration:</u> <i>Oral vs. subcutaneous injection</i>  <u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 100 units/mL or 500 units/mL</i>  <u>Dosage Form:</u> <i>Capsule vs. injectable</i>
Menactra (meningococcal vaccine) for intramuscular injection	Look alike	N/A	0.5 mL as a single intramuscular injection	<u>Route of Administration:</u> <i>Oral vs. intramuscular injection</i>  <u>Dosage Form:</u> <i>Capsule vs. injectable</i>

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

<b>Product name with potential for confusion</b>	<b>Similarity to Namenda XR</b>	<b>Strength</b>	<b>Usual Dosage &amp; Administration</b>	<b>Differentiating Product Characteristics (Namenda XR vs. Product)</b>
<b>Namenda XR (memantine hydrochloride)</b>	N/A	<b>7 mg, 14 mg, 21 mg, 28 mg</b>	<b>28 mg once daily</b>	N/A
Neumega (oprelvekin) powder for injection	Look alike and sound alike	5 mg/vial	50 mcg/kg given once daily subcutaneous as a single injection	<u>Route of Administration:</u> <i>Oral vs. subcutaneous injection</i> <u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 5 mg/vial</i> <u>Dosage Form:</u> <i>Capsule vs. powder for injection</i>
Remicade (infliximab) lyophilized powder for injection	Look alike	100 mg/vial	3 mg/kg intravenous infusion. Repeat at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Patients with incomplete response may be dose adjusted up to 10 mg/kg as often as every 4 weeks.	<u>Route of Administration:</u> <i>Oral vs. intravenous infusion</i> <u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 100 mg/vial</i> <u>Dosage Form:</u> <i>Capsule vs. powder for injection</i>
Rescula (unoprostone isopropyl) ophthalmic drops	Look alike	0.15%	Instill one drop in the affected eye(s) twice daily	<u>Route of Administration:</u> <i>Oral vs. ophthalmic</i> <u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 0.15%</i> <u>Dosage Form:</u> <i>Capsule vs. ophthalmic solution</i>
Nexavar (Sorafenib Tosylate) Tablets	Look alike	200 mg	400 mg by mouth twice daily.	<u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 200 mg</i> <u>Usual Dose:</u> <i>28 mg vs. 400 mg</i> <u>Frequency:</u> <i>Once daily vs. twice daily</i>
Raniclor (cefaclor) Chewable Tablets	Look alike	125 mg, 187 mg, 250 mg, 375 mg	Adult dose is 250 mg q8h. For more severe infections, doses may be doubled.  In pediatrics, 20 – 40 mg/kg/day in divided doses every 8 hours up to max of 1g/day.	<u>Strength:</u> <i>7 mg, 14 mg, 21 mg, or 28 mg vs. 125 mg, 187 mg, 250 mg, or 375 mg</i> <u>Usual Dose:</u> <i>28 mg vs. 250 mg</i> <u>Frequency:</u> <i>Once daily vs. every eight hours</i>

Product name with potential for confusion	Similarity to Namenda XR	Strength	Usual Dosage & Administration	Differentiating Product Characteristics (Namenda XR vs. Product)
Namenda XR (memantine hydrochloride)	N/A	7 mg, 14 mg, 21 mg, 28 mg	28 mg once daily	N/A
Renvela (sevelamer carbonate) Tablets or Powder for Oral Suspension	Look alike	800 mg tablet, 800 mg/packet, 2.4 GM/packet	Dosed three times a day with meals. Dose is individualized depending on serum phosphorus levels.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 800 mg or 2.4 GM <u>Usual Dose:</u> 28 mg vs. 800 mg or otherwise individualized <u>Frequency:</u> Once daily vs. three times a day
Momentum (magnesium salicylate) Caplets or Momentum (aspirin and phenyltoloxamine citrate) Tablets OTC products	Look alike	magnesium salicylate: 40 mg, 580 mg aspirin and phenyltoloxamine citrate: 500 mg/15 mg	magnesium salicylate: Take 2 caplets every 6 hours while symptoms persist. aspirin and phenyltoloxamine citrate: Per Pfizer Consumer Healthcare, name of this product was divested in 1996.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 40 mg or 580 mg <u>Usual Dose:</u> 28 mg vs. 2 caplets <u>Frequency:</u> Once daily vs. every six hours
Neurontin (gabapentin) Capsules, Tablets, and Oral Solution	Look alike	<u>Capsules:</u> 100 mg, 300 mg, 400 mg, 800 mg <u>Tablets:</u> 600 mg, 800 mg <u>Solution:</u> 250 mg/5 mL	For adults: 600 mg three times a day. For pediatric patients: 40 mg/kg/day given in divided doses three times a day.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 100 mg, 300 mg, 400 mg, or 800 mg <u>Usual Dose:</u> 28 mg vs. 600 mg <u>Frequency:</u> Once daily vs. every six hours
Nexcede *** (ketoprofen) Soluble Film	Look alike	12.5 mg	Place one oral soluble film on top of the tongue and allow to dissolve every 4 to 6 hours as symptoms persist.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 12.5 mg <u>Usual Dose:</u> 28 mg vs. one film <u>Frequency:</u> Once daily vs. every four to six hours

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

<b>Product name with potential for confusion</b>	<b>Similarity to Namenda XR</b>	<b>Strength</b>	<b>Usual Dosage &amp; Administration</b>	<b>Differentiating Product Characteristics (Namenda XR vs. Product)</b>
<b>Namenda XR (memantine hydrochloride)</b>	N/A	<b>7 mg, 14 mg, 21 mg, 28 mg</b>	<b>28 mg once daily</b>	N/A
Nicomide (nicotinamide, zinc, copper, and folic acid) Tablets	Look alike	750/25/1.5/0.5 mg	One tablet by mouth once or twice daily.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 750/25/1.5/0.5 mg  <u>Usual Dose:</u> 28 mg vs. one tablet
Revatio (sildenafil citrate) Tablets	Look alike	20 mg	20 mg three times a day by mouth taken 4-6 hours apart.	<u>Strength:</u> 7 mg, 14 mg, 21 mg, or 28 mg vs. 20 mg  <u>Usual Dose:</u> 28 mg vs. 20 mg  <u>Frequency:</u> Once daily vs. every four to six hours
Sinusalia (Belladonna, Sanguinaria canadensis, Spigelia anthelmia) Tablets	Look alike	N/A	Two tablets every 2 hours up to 6 times a day.	<u>Usual Dose:</u> 28 mg vs. 2 tablets  <u>Frequency:</u> Once daily vs. every two hours

**Appendix J:** Potentially confusing names unlikely to lead to medication errors

<b>Proposed Name:</b> Namenda (memantine hydrochloride) XR Capsules	<b>Strength:</b> 7 mg, 14 mg, 21 mg, 28 mg	<b>Usual Dose:</b> 28 mg once daily
<b>Failure Mode:</b> Name confusion	<b>Causes (can be multiple)</b>	<b>Prevention of Failure Mode</b>
Avandia (rosiglitazone) XR *** Tablets  <b>Strengths:</b> 2 mg, 4 mg, 8 mg  <b>Usual Dose:</b> 1 tablet once daily	<b>Orthographic Similarities:</b> Both names contain the modifier “XR”  Both names contain an upstroke “d”  Both root names contain 7 characters  <b>Overlap in Frequency:</b> Both are dosed once daily	Sufficient product characteristic differences minimize the likelihood of medication error in the usual practice setting.  <b>Rationale:</b> Although there are orthographic similarities between the two names, there is no overlap in product strengths or in usual dose between these two products. Because both products are available in multiple strengths, any prescription written without a strength specified would require a pharmacist to call the prescribing provider to verify the prescription.  Avandia XR is currently in IND phase and has not submitted a request for proprietary name review. It is being studied up to 8 mg once a day at this time.
Namenda (memantine hydrochloride) Tablets  <b>Strengths:</b> 5 mg, 10 mg, 2 mg/mL  <b>Usual Dose:</b>  The recommended starting dose is 5 mg once daily. The recommended maintenance dose is 10 mg twice daily	<b>Orthographic and Phonetic Similarities:</b> Both names contain the root “Namenda”  <b>Route of Administration:</b> Both products are given orally  <b>Overlap in Frequency:</b> As part of the titration phase, Namenda can be initially dosed once daily which overlaps with the once daily dosing of Namenda XR	Sufficient product characteristic differences minimize the likelihood of medication error in the usual practice setting.  <b>Rationale:</b> Although these names are identical, there is no overlap in product strengths or in usual dose between the two products. Because both products are available in multiple strengths, any prescription written without a strength specified would require a pharmacist to call the prescribing provider to verify the prescription. In addition, the order for Namenda oral solution may be ordered in teaspoons or milliliters, which would differentiate it from Namenda XR which is only proposed to be available as capsules.

<p>Neurodex<sup>***</sup> (dextromethorphan hydrobromide and quinidine sulfate) Capsules</p> <p><b>Strengths:</b> 30 mg/30 mg</p> <p><b>Usual Dose:</b> 1 capsule every 12 hours</p>	<p><b>Orthographic Similarities:</b></p> <p>Both names begin with the name “N”</p> <p>Both names contain an upstroke “d”</p> <p><b>Route of Administration:</b></p> <p>Both products are given orally</p>	<p>Differences in product characteristics as well as orthographic differences minimize the likelihood of medication error in the usual practice setting.</p> <p><b>Rationale:</b></p> <p>Neurodex is a combination product that is available in a 30 mg/30 mg strength. This is different from any available strength for Namenda XR. In addition, Neurodex is given twice daily 12 hours apart whereas Namenda XR is only given once daily.</p> <p>The suffix for the two names are sufficiently different with “va” versus “dex.”</p> <p>Neurodex is not an approved proprietary name.</p>
<p>Revonto<sup>***</sup> (dantrolene sodium) Injectable</p> <p><b>Strengths:</b> 20 mg per vial</p> <p><b>Usual Dose:</b> Continuous rapid IV push beginning at a minimum dose of 1 mg/kg, and continuing until symptoms subside or the maximum cumulative dose of 10 mg/kg has been reached.</p>	<p><b>Orthographic Similarities:</b></p> <p>Revonto contains an upstroke “t” and Namenda XR contains an upstroke “d”</p> <p>Both names contain 7 characters</p>	<p>Orthographic differences and differences in product characteristics minimize the likelihood of medication error in the usual practice setting.</p> <p><b>Rationale:</b></p> <p>The prefix for the two names are distinctly different with “Rev” for Revonto and “Nam” for Namenda XR. In addition, Namenda XR contains the modifier “XR” whereas Revonto does not contain a modifier.</p> <p>These two products are given by different routes of administration. Revonto is administered by IV push whereas Namenda XR is given orally. In addition, there is no overlap in product strength between the two products.</p> <p>Revonto is not an approved proprietary name.</p>

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22525	ORIG-1	FOREST LABORATORIES INC	NAMENDA XR(MEMANTINE HCL)ER CAPSULES

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

/s/

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12/29/2009

DENISE P TOYER  
12/29/2009