CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209410Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	December 4, 2017
Application Type and Number:	NDA 209410
Product Name and Strength:	Osmolex ER (amantadine) Extended-release tablets 129 mg, 193 mg, 258 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Osmotic Pharmaceuticals
Panorama #:	2017- 18095842
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Osmolex ER, which was found acceptable under NDA 209410 on June 30, 2017.[a] The established name of the product was originally presented as the salt, amantadine hydrochloride, with strengths of 160 mg, 240 mg, and 320 mg per extended-release tablet. Based on the recommendation by the Agency, Osmotica Pharmaceuticals revised the strength of the product to reflect the active moiety, amantadine, as the established name with revised strengths of 129 mg, 193 mg, and 258 mg. Thus, the applicant resubmitted the proposed proprietary name, Osmolex ER, on October 5, 2017, to reflect the change in the strength presentation.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in the strength from160 mg, 240 mg, and 320 mg to 129 mg, 193 mg, and 258 mg.

Additionally, since Osmolex ER is being proposed in strengths that are not commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Osmolex ER that were not identified in POCA, and found to have an overlap in strength with Osmolex ER. Our search did not identify any names.[b]

We also searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. Our search did not identify any USAN stems in the proposed proprietary name.[c]

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 30, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on November 30, 2017, they stated no additional concerns with the proposed proprietary name, Osmolex ER.

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[a] Morris, Chad. Proprietary Name Review for Osmolex ER (NDA 209410). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JUN 30. Panorama No. 2017-14237053.

[b] eDRLS searched October 11, 2017

[c] USAN stem list searched October 11, 2017

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Osmolex ER, is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 5, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. Electronic Drug Registration and Listing System (eDRLS) database

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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

/s/

JOHN C MORRIS
12/04/2017

LOLITA G WHITE
12/04/2017

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	June 30, 2017
Application Type and Number:	NDA 209410
Product Name and Strength:	Osmolex ER (amantadine hydrochloride) Extended-Release tablet 160 mg, 240 mg, 320 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Osmotica Pharmaceutical
Panorama #:	2017-14237053
DMEPA Primary Reviewer:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Osmolex ER, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by the (b) (4). for this product.

1.1 REGULATORY HISTORY

Osmotica previously submitted the proposed proprietary name, Osmolex*** on December 22, 2010. We found the name, Osmolex*** conditionally acceptable in review 2011-62[a] dated June 21, 2011. However, since the proposed product is an extended-release dosage form and the proposed name, Osmolex*** did not contain a modifier to convey the extended-release properties of the product, we recommended Osmotica assess the risk of wrong technique medication errors (that is, chewing, splitting, crushing) prior to submitting this name with their marketing application.

Thus, Osmotica submitted the name, Osmolex ER, for review on April 17, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 17, 2017 proprietary name submission.

- Intended Pronunciation: Oz mole x ee are
- Active Ingredient: amantadine hydrochloride
- Indication of Use:
  - Treatment of (b) (4) Parkinson's disease, (b) (4) (b) (4)
  - Treatment of drug-induced extrapyramidal reactions
- Route of Administration: oral
- Dosage Form: extended-release tablet
- Strength: 160 mg, 240 mg, 320 mg
- Dose and Frequency: 1 tab (160 mg, 240 mg or 320 mg) once daily
- How Supplied:
  - Bottles of 30 tablets and (b) (4) tablets

[a] Baugh, D. Proprietary Name Review for Osmolex (amantadine) IND 103538. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 21 JUN 2011. RCM No.: 2011-62.

- Unit-dose Blister cards of 10 tablets

- Storage: Controlled room temperature
- Container and Closure Systems: Foil backed blisters and (b) (4) bottles
- Reference Listed Drug: Symmetrel Syrup (NDA 016023)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Osmolex ER in their submission. This proprietary name is comprised of a root name, Osmolex, and the modifier, ER. We provide our assessment of the modifier, ER, in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE May 4, 2017 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Sixty-nine practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Assessment of the proposed modifier, ER

Osmolex ER is a proposed extended-release tablet administered once daily. The proposed strengths are 160 mg, 240 mg, and 320 mg. (b) (4)

[b] USAN stem search conducted on May 30, 2017.

(b) (4) According to Osmotica, they propose to use the modifier, 'ER', to mean 'extended-release'.

We note that the use of a modifier to convey that the product is an extended-release dosage form is contingent upon the product meeting the Agency's criteria for this designation. Assuming these criteria are met, products with the modifier, ER have been approved in cases where a product is administered every 12 hours, twice daily, or once daily. Based on ISMP's List of Products with Drug Name Suffixes , the modifier "ER" is typically used to convey the meaning "extended release" for products with modified-release formulations. In this case, Osmolex ER is a modified dosage form that will be dosed once daily; therefore, the use of the modifier, ER, is consistent with its existing meaning and is appropriate for conveying this characteristic of the product formulation. Thus, we find the use of the modifier, 'ER', for the proposed proprietary name, Osmolex ER, is acceptable.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search identified 216 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. These names are included in Table 1 below.

2.2.7 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Osmolex ER, will be available in 160 mg, 240 mg, and 320 mg strengths. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. None of the names identified in the eDRLS database are likely to be confused due to notable spelling, orthographic and phonetic differences. The names identified in our eDRLS search are listed in Appendix I.

2.2.8 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	12
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	222
Low similarity name pair: combined match percentage score ≤54%	11

2.2.9 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 245 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.10 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on June 28, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on June 28, 2017, they stated no additional concerns with the proposed proprietary name, Osmolex ER.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Corwin Howard, OSE project manager, at 240-402-8654.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 17, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. 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. [c]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

[d] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

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

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

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

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg

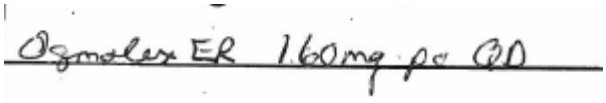
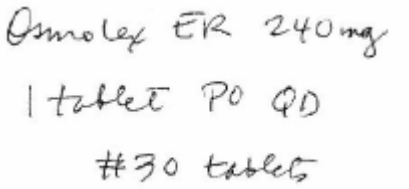
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Osmolex ER Study (Conducted on May 15, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Osmolex ER 240 mg 1 tab po qd #30 tabs
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 2 Rx Studies Report)

Study Name: Osmolex ER
As of Date 5/30/2017

296 People Received Study
69 People Responded

Study Name: Osmolex ER

OUTPATIENT	VOICE	INPATIENT
OSMOLEX ER (21)	HOSVOLEX ER (1)	OGMALEX ER (1)
SOMOLEX ER (1)	OSMALEX ER (2)	OGMLOEX ER (1)
	OSMERLEX ER (1)	OGMOLEX ER (9)
	OSMOLAX (1)	OQMOLEX ER (2)
	OSMOLAX ER (1)	OSMELOX ER (1)
	OSMOLEX ER (12)	OSMOLEX ER (14)
		OZMOLEX ER (1)

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name: Osmolex ER Established name: amantadine HCl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet (160 mg, 240 mg or 320 mg) once daily**	**POCA Score (%) Root name**	**POCA Score (%) Root name plus modifier**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Osmolex***	100	82	This is the root name under review.
2.	Osmolex Er***	82	100	This is the name under review.
3.	Embolex	77	62	International product formerly marketed in Austria.
4.	Senolax	74	60	When comparing the root name, Osmolex, to the name Senolax, the prefixes ('Osm-' vs 'Sen-') of this name pair have sufficient orthographic differences. When comparing the root name, Osmolex, to the name Senolax, the first ('oz-' vs 'sen-') and second ('-mole-' vs '-o-') syllables of this name pair sound different. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included.
5.	Asmalix	74	58	The name, Osmolex ER, contains a modifier which further differentiates the name pair if included. There is no strength overlap and Osmolex is an oral tablet available in multiple strengths (160 mg, 240 mg, 320 mg) that will be included on the prescription. Asmalix is a single strength oral elixir (80 mg/15mL) and prescribers are likely to indicate the units of measurement as "mL" on the prescription. Asmalix is deactivated per RedBook and has no listing on Drugs@FDA or Facts and Comparisons. Considering that there are branded generic equivalents available, we find it unlikely that the name Asmalix will be used by prescribers to order theophylline elixir on a prescription .

No.	**Proposed name: Osmolex ER Established name: amantadine HCl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet (160 mg, 240 mg or 320 mg) once daily**	**POCA Score (%) Root name**	**POCA Score (%) Root name plus modifier**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
6.	Osmolite	74	61	When comparing the root name, Osmolex, to the name Osmolite, the suffixes ('lex' vs lite') have sufficient orthographic differences. When comparing the root name, Osmolex, to the name Osmolite the third syllables ('x' vs 'ite') have sufficient phonetic differences. The proposed name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
7.	Vasolex	72	60	When comparing the root name, Osmolex, to the name Vasolex, the prefixes ('Osm-' vs 'Vas-') of this name pair have sufficient orthographic differences. When comparing the root name, Osmolex, to the name Vasolex, the first ('Oz-' vs 'Vaz-') and second ('-mole' vs '-o'), syllables of this name pair have sufficient phonetic differences. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included.

No.	**Proposed name: Osmolex ER Established name: amantadine HCl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet (160 mg, 240 mg or 320 mg) once daily**	**POCA Score (%) Root name**	**POCA Score (%) Root name plus modifier**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
8.	MSM Plex	72	58	When comparing the root name, Osmolex, to the name MSM Plex, this name pair has sufficient orthographic differences. The beginning letter ('O-' vs 'M-') have different shapes. In addition, the name MSM Plex contains two words and Osmolex is one word which makes the name appear different when written. When comparing the root name, Osmolex, to the name MSM Plex, the first ('Oz-' vs 'Em-'), second ('-mole' vs '-ess'), and third ('-x' vs '-em') syllables of this name pair have sufficient phonetic differences. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included. The product characteristics provide further differences. Specifically, Osmolex ER is available is a single ingredient product available in multiple strengths while MSM Plex is a multiple ingredient product available in one strength. As such the product strength for Osmolex ER will need to be included on the written prescription to identify the prescribed strength. In addition, the doses of the two products (160 mg, 240 mg, 320 mg or 1 tablet once daily vs. Use as directed) do not overlap.
9.	Mucolex	70	57	Mucolex is the name of an international product formerly marketed in Portugal, Hong Kong, Ireland, Malaysia, and Thailand.

No.	Proposed name: Osmolex ER Established name: amantadine HCl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet (160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
10.	Sebulex	70	56	When comparing the root name, Osmolex, to the name Sebulex, the prefixes ('Osm-' vs' Seb-') of this name pair have sufficient orthographic differences. When comparing the root name, Osmolex, to the name Sebulex, the first ('oz-' vs 'seb-') and second ('-mole-' vs '-you-') syllables of this name pair have sufficient phonetic differences. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included.

No.	**Proposed name: Osmolex ER Established name: amantadine HCl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet (160 mg, 240 mg or 320 mg) once daily**	**POCA Score (%) Root name**	**POCA Score (%) Root name plus modifier**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
11.	Osmoflex	89	78	When comparing the root name, Osmolex, to the name Osmoflex, the infixes ('lex-' vs 'flex-') of this name pair have some orthographic differences. The name Osmolex has one upstroke letter ('l') while the name Osmoflex has two upstroke letters ('-fl'). When comparing the root name, Osmolex, to the name Osmoflex, the third ('lex-' vs 'flex-') syllables of this name pair have differences in the onset sounds of these syllables. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included. The differences in product characteristics minimize the likelihood for confusion between Osmolex ER and Osmoflex. There are no overlaps in strength, dose, route, or dosage form. Specifically, Osmolex ER is a single ingredient oral tablet available in multiple strengths (160 mg, 240 mg, 320 mg) while Osmoflex is a single ingredient topical cream product available in one strength (1.3%). In addition, the doses differ when prescribing the two products (160 mg, 240 mg, 320 mg once daily vs. Use as directed or apply to affected area not more than 3 to 4 times daily). As such, the product strength and/ or dose for Osmolex ER will need to be included on the written prescription, which provides additional differentiation.
12.	Ostilox	71	56	Veterinary product.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
N/A			

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	MoodPlex	69	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, MoodPlex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
14.	Folex	68	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Folex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
15.	Complex 15	67	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Complex. Both names contain a different modifier (ER vs 15), which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	Myoflex	67	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Myoflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
17.	Solurex	67	58	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Solurex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
18.	Osmovist 190	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Osmovist. Both names contain a different modifier (ER vs 190), which further differentiates the name pair if included.
19.	Osmovist 240	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Osmovist. Both names contain a different modifier (ER vs 240), which further differentiates the name pair if included.
20.	Esmolol	66	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Esmolol. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
21.	(b) (4)***	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, (b) (4)***. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
22.	Salex	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Salex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
23.	Simulect	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Simulect. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
24.	Skelex	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Skelex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
25.	Tussplex	66	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Tussplex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
26.	Asmanex	65	65	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Asmanex. The name, Osmolex contains a single up stroke ('l') which is absent in the name Asmanex. This up stroke letter also makes the name Osmolex have a different shape from the name, Asmanex when written. The name, Osmolex, contains a modifier ER. The marketed product, Asmanex, includes the modifier, HFA or Twisthaler. The different modifiers further differentiate the name pair if included. The differences in product characteristics minimize the likelihood for confusion between Osmolex ER and Asmanex. There are no overlaps in strength, dose, or dosage form. Specifically, Osmolex ER is a single ingredient oral tablet available in multiple strengths (160 mg, 240 mg, 320 mg) and Asmanex HFA and Asmanex Twisthaler are inhalation aerosols for oral inhalation available in multiple strengths (100 mcg, 110 mcg, 200 mcg, 220 mcg). In addition, the doses differ between the two products (160 mg, 240 mg, 320 mg once daily vs. 1 to 4 inhalations divided once or twice daily). Therefore, the strength and/or dose would have to be specified to dispense/administer either medication as intended, which provides additional differentiation.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
27.	Zorvolex	65	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Zorvolex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
28.	Osmolite HN	64	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Osmolite. Both names contain a different modifier (ER vs HN), which further differentiates the name pair if included.
29.	VasoFlex	64	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Vasoflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
30.	C Complex	64	64	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, C Complex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
31.	Dosaflex	64	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Dosaflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
32.	Livolex	64	52	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Livolex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
33.	Lophlex	63	51	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Lophlex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
34.	Osmolite 1.2 CAL	62	66	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Osmolite. Both names contain a different modifier (ER vs 1.2 CAL), which further differentiates the name pair if included.
35.	Orlex	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Orlex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
36.	Osmoglyn	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Osmoglyn. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
37.	Osmoprep	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Osmoprep. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
38.	Mycelex	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Mycelex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
39.	Bioflexor	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Bioflexor. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
40.	Femilax	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Femilax. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
41.	Folplex	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Folplex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
42.	Iodoflex	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Iodoflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
43.	Mycelex-3	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Mycelex. Both names contain a different modifier (ER vs 3), which further differentiates the name pair if included.
44.	Mycelex-7	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Mycelex. Both names contain a different modifier (ER vs 7), which further differentiates the name pair if included.
45.	Oxtellar Xr	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Oxtellar. Both names contain a different modifier (ER vs XR), which further differentiates the name pair if included.
46.	Solv X	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Solv X. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
47.	Staflex	62	62	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Staflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
48.	Folplex 2.2	62	51	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Folplex. Both names contain a different modifier (ER vs 2.2), which further differentiates the name pair if included.
49.	Onyplex	62	50	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Onyplex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
50.	Ismo Retard	61	61	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Ismo. Both names contain a different modifier (ER vs Retard), which further differentiates the name pair if included.
51.	Lescol Xl	61	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Lescol. Both names contain a different modifier (ER vs Xl), which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
52.	Senna Lax	61	61	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Senna Lax. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
53.	Sennalax	61	61	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Sennalax. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
54.	Sennalax S	61	61	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Sennalax. Both names contain a different modifier (ER vs S), which further differentiates the name pair if included.
55.	OPTILETS-500	60	48	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Optilets. Both names contain a different modifier (ER vs 500), which further differentiates the name pair if included.
56.	Venelex	60	60	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Venelex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
57.	NEO-Cholex	60	54	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Cholex. Both names contain a different modifier (ER vs NEO), which further differentiates the name pair if included.
58.	Complex B	59	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Complex B. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
59.	Flexeril	59	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Flexeril. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
60.	Plasma-Plex	59	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Plasma-Plex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
61.	Norflex	59	59	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Norflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
62.	Osteo Bi-Flex	58	58	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Osteo Bi-Flex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
63.	Azelex	58	58	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Azelex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
64.	Salflex	58	58	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Salflex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
65.	Vasoflex D1	58	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Vasoflex D1. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
66.	Onsolis	57	57	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Onsolis. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
67.	Ana-lex	57	57	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Ana-lex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
68.	Solesta	57	57	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Solesta. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
69.	Endosol Extra	57	57	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Endosol. Both names contain a different modifier (ER vs Extra), which further differentiates the name pair if included.
70.	Z-Plex	57	45	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Z-Plex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
71.	Osmitrol	56	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Osmitrol. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
72.	Asper-Flex	56	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Asper-Flex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included
73.	Otomax	56	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Otomax. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
74.	Promolaxin	56	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Promolaxin. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
75.	Osteolite	56	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Osteolite. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
76.	Cylex	56	44	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Cylex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
77.	I-Valex-2	56	44	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, I-Valex-2. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
78.	Ocuflox	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Ocuflox. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
79.	Bisa-Plex	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Bisa-Plex. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
80.	Ed Flex	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Ed-Flex. The name, Osmolex ER, contains a modifier which further differentiates the name pair if included
81.	Flex24	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Flex. Both names contain a different modifier (ER vs 24), which further differentiates the name pair if included.

No.	Proposed name: Osmolex ER Established name: amantadine hcl Dosage form: extended-release tablet Strength(s): 160 mg, 240 mg, 320 mg Usual Dose: 1 tablet(160 mg, 240 mg or 320 mg) once daily	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
82.	Folex Pfs	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the root name, Folex. Both names contain a different modifier (ER vs Pfs), which further differentiates the name pair if included.
83.	Locholest	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, Locholest. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
84.	Rythmol Sr	55	55	This name pair has sufficient orthographic and phonetic differences, when comparing the name, Osmolex ER, to the name, Rythmol Sr. .
85.	(b) (4)***	41	56	This name pair has sufficient orthographic and phonetic differences, when comparing the root name, Osmolex, to the name, (b) (4)***. The name, Osmolex ER, contains a modifier, which further differentiates the name pair if included.
86.	(b) (4)***	38	58	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
87.	ARKO-LAX	54	45
88.	BISA-LAX	52	40

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
89.	DOCULAX	54	42
90.	ISMO	40	30
91.	I-VALEX-1	54	44
92.	OMEPRAZOLE	40	48
93.	ORNIDEX	54	47
94.	OZURDEX	52	46
95.	STARLIX	54	46
96.	UNIFLEX	54	44
97.	ZANAFLEX	50	43

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Failure preventions
98.	Ascalix	58	58	International product formerly marketed in United Kingdom.
99.	BioFlex	59	48	International product formerly marketed in Chile.
100.	Biolex	62	50	Name identified in external study. Unable to find product characteristics in internal databases.
101.	Broflex	59	59	International product marketed in India and United Kingdom.
102.	Bromoplex Dm	55	55	Brand discontinued with no generic equivalent available
103.	Brovex Sr	56	56	Brand discontinued with no generic equivalent available
104.	Colrex	60	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Combiflex	58	58	Brand discontinued with no generic equivalent available.
106.	Combiflex Es	58	58	Brand discontinued with no generic equivalent available.
107.	Comox	55	55	International product marketed in Thailand.
108.	Convulex	60	60	International product marketed in several foreign countries.

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Failure preventions
109.	CosaFlex	64 (70 O)	56	Name identified in external study. Unable to find product characteristics in internal databases.
110.	Dicloflex Sr	56	56	International product formerly marketed in United Kingdom.
111.	Dorflex	59	59	International product marketed in Brazil.
112.	Emflex	62	62	International product marketed in United Kingdom.
113.	Epidiolex***	56	56	Proposed proprietary name for IND 120055 found unacceptable by DMEPA (OSE# 2015-792227). The alternate name, (b) (4) *** was conditionally approved (2016-7400543) for this application.
114.	Flex-10	55	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
115.	HemaFlex	56	48	Name identified in external study. Unable to find product characteristics in internal databases.
116.	Hemoplex F	59	57	Brand discontinued with no generic equivalent available.
117.	Hooflex	66	66	Product is not a drug. It is different types of barrier protectants and dressings.
118.	ImmuPlex	62	50	Name identified in external study. Unable to find product characteristics in internal databases.
119.	Indoflex	59	59	International product marketed in South Africa and United Kingdom.
120.	Iro-Plex	58	50	International product formerly marketed in Phillipines.
121.	Isovex	64	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
122.	Malix	56	56	International product formerly marketed in the UK.
123.	Marlexate	56	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
124.	Mepilex	59	48	Product is not a drug. It is different types of barrier protectants and dressings.
125.	Mobiflex	62	62	International product marketed in Canada, Indonesia, Hong Kong, Ireland, New Zealand, the UK, Australia, South Africa, Italy, Malaysia, Singapore, and Thailand.
126.	molasses	61	61	This is not a drug, it is a thick, dark brown syrup obtained from raw sugar during the refining process

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Failure preventions
127.	Molcer	60	60	International product marketed in the United Kingdom.
128.	Nalex	56	56	Brand discontinued with no generic equivalent available
129.	Norel Ex	60	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	Noxyflex-S	55	55	International product marketed in the United Kingdom.
131.	Orelox	59	59	International product marketed in Germany, Brazil, France, Italy, Mexico, South Africa, and Turkey.
132.	Osmocyte	61	50	Name identified in external study. Unable to find product characteristics in internal databases.
133.	Parvolex	58	58	International product marketed in Canada, South Africa, Greece, Ireland and the United Kingdom.
134.	Pemolert	55	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
135.	Phenolax	64	64	International product marketed in Thailand.
136.	Proflex	59	59	International product marketed in United Kingdom, South Africa, and Philippines.
137.	Prolex	62	62	Product discontinued with no generics available
138.	Prolex D	58	58	Product discontinued with no generics available
139.	Salinex	56	56	Discontinued product with no generic equivalents available.
140.	Sanorex	66	56	Discontinued product with no generic equivalents available.
141.	SedaPlex	58	50	Name identified in external study. Unable to find product characteristics in internal databases.
142.	Senalax	62 (75 P)	50	International product formerly marketed in the Czech Republic, Poland, and Phillipines
143.	Senalax SS	62 (75 P)	50	International product formerly marketed in the Czech Republic, Poland, and Phillipines
144.	Serdolect	58	58	International product marketed in several foreign countries.
145.	Solostar	56	56	Product is not a drug name. This is a modifier added to insulin products to designate a cartridge system. There are multiple insulins with the Solostar modifier (Apidra, Lantus, Toujeo), so the root name must be indicated thus providing differentiation.

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier	Failure preventions
146.	Sonamox	58	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
147.	StimuPlex	60	56	Name identified in external study. Unable to find product characteristics in internal databases.
148.	Stomax	56	56	Brand discontinued with no generic equivalent available.
149.	Stool-Lax	68	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
150.	Sumox	62	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
151.	Superoxol	55	55	International product formerly marketed in Germany.
152.	Synflex	61	61	International product marketed in Canada, Indonesia, Hong Kong, Ireland, New Zealand, the UK, Australia, South Africa, Italy, Malaysia, Singapore, and Thailand.
153.	Synovex	66	66	Veterinary product.
154.	Sytobex	58	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
155.	Tobralex	58	58	International product marketed in UK
156.	Volmax	56	56	Product is not a drug. It is different types of dressings and bandages.
157.	Unna-Flex	53	42	Brand discontinued with no generic equivalent available
158.	Xolex	70	56	Product discontinued. There are no generics available.
159.	Xolox	60	60	Brand discontinued with no generic equivalent available

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[e].

[e] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
160.	Acnotex	56	56
161.	Amiloxate	56	56
162.	Anorex	56	56
163.	Anorex-Sr	61	61
164.	ASPIRLOX	56	50
165.	Aspir-Mox	56	56
166.	Avelox	55	55
167.	Bisco-Lax	60	60
168.	Bismarex	60	55
169.	Bisolax	64	64
170.	Bromo Seltzer	57	57
171.	Busulfex	57	57
172.	Casodex	59	59
173.	CHOLVEX	60	48
174.	Colax	56	56
175.	Denorex	56	56
176.	Dostinex	55	55
177.	EASY-LAX	55	44
178.	Estomax	60	60
179.	EXOREX	59	51
180.	Faslodex	56	56
181.	Fosamax	59	59
182.	Fostex	58	58
183.	Fostex Bar	58	58
184.	Fostex Bar 10%	58	58
185.	Hemmorex	62	62
186.	Imovax	55	55
187.	ISODEX 2.0	62	50
188.	Isolyte P	56	56
189.	Isolyte S	60	60
190.	Isotrex	60	60
191.	Istodax	56	56
192.	Lortab Elixir	55	55
193.	Lortuss Ex	55	55
194.	Lotemax	56	56
195.	Lusonex	62	62
196.	Maalox	56	56
197.	Mefenorex	58	56
198.	Melanex	58	58
199.	Mesnex	57	57

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
200.	Mirapex Er	56	56
201.	Moexipril	56	56
202.	Nasonex	56	56
203.	PHOSPHA-LAX	58	49
204.	Plasma-Lyte R	56	56
205.	POLOX	57	44
206.	Poloxamer	63	63
207.	Poloxamer 124	63	63
208.	Poloxamer 181	63	63
209.	Poloxamer 182	63	63
210.	Poloxamer 184	63	63
211.	Poloxamer 188	63	63
212.	Poloxamer 234	63	63
213.	Poloxamer 237	63	63
214.	Poloxamer 331	63	63
215.	Poloxamer 335	63	63
216.	Poloxamer 338	63	63
217.	Poloxamer 403	63	63
218.	Poloxamer 407	63	63
219.	Poly-Dex	56	56
220.	Polyester-10	58	58
221.	Polyester-7	58	58
222.	Polymox	56	56
223.	RESTORE-X	60	57
224.	Sedalmex	62	62
225.	Senox	56	56
226.	Sil Tex	60	60
227.	Smileguard	56	56
228.	SOF-LAX	63	50
229.	(b) (4)***	56	56
230.	Soloxine	56	58
231.	Soltamox	56	56
232.	Solurex La	58	58
233.	Sominex	64	64
234.	Sonorx	57	57
235.	Soothanol X2	58	58
236.	SORBULAX	61	54
237.	Sorilux	57	57
238.	STONEX	62	50
239.	SULFOLAX	59	50

No.	Name	POCA Score (%) Root name	POCA Score (%) Root name plus modifier
240.	Synovex C	58	58
241.	Synovex One	56	56
242.	Theolixir	62	62
243.	Tomudex	63	63
244.	Visonex	56	56
245.	Zoladex	58	58

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
246.	Alvesco
247.	Arcalyst
248.	Armour Thyroid
249.	Betapace
250.	BETAPACE AF
251.	CALAN SR
252.	Cardizem
253.	Cardizem CD
254.	CARDIZEM LA
255.	Cartia
256.	Childrens Silapap
257.	Covera-HS
258.	Dilacor
259.	DILT-CD
260.	DILTIAZEM HYDROCHLORIDE
261.	Diltiazem Hydrochloride Extended Release
262.	DILTZAC
263.	Diovan
264.	Docetaxel
265.	Dopamine HCl
266.	Dopamine Hydrochloride and Dextrose
267.	ENTERO Vu 24%
268.	FACTIVE
269.	FENOFIBRATE
270.	Fludeoxyglucose F 18
271.	INDERAL
272.	Inderal LA

No.	Name
273.	Iodixanol
274.	ISOPTIN
275.	Lofibra
276.	Matzim LA
277.	Nadolol
278.	NITRO-DUR
279.	OMNIPAQUE
280.	OxyContin
281.	Oxygen Size C
282.	Phenylephrine HCl
283.	Propranolol Hydrochloride
284.	Sorine
285.	Sotalol Hydrochloride
286.	SUPRANE
287.	TAZTIA
288.	Tecfidera
289.	Theophylline in Dextrose
290.	TIAZAC
291.	Tiazac Extended Release
292.	Tricor
293.	TRIGLIDE
294.	Valsartan
295.	Verapamil
296.	VERAPAMIL HYDROCHLORIDE
297.	Verelan
298.	Visipaque
299.	Vivaglobin
300.	ZELBORAF

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/s/

JOHN C MORRIS
06/30/2017

LOLITA G WHITE
06/30/2017

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Date:	June 21, 2011
Application Type/Number:	IND 103538
Through:	Todd Bridges, RPh, Acting Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD, BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Osmolex (Amantadine) Extended-release Tablets (b) (4), 160 mg, 240 mg, 320 mg
Sponsor:	Osmotica Pharmaceutical
OSE RCM #:	2011-62

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

CONTENTS

EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Osmolex for Amantadine Extended-release Tablets. We have completed our review of this proposed proprietary name and have concluded that this name is acceptable from a promotional, sound and look-alike perspective. However, your proposed proprietary name lacks a modifier to convey the extended-release properties of the product (e.g., ER, XR, SR, and CR). Specifically, wrong technique errors (e.g., chewing, splitting, or crushing) with extended release tablets marketed under various proprietary names without modifiers have been previously identified in post marketing reporting. Many patients were instructed by their physician to crush, chew or split the tablet despite the inclusion of warning statements in the product labeling advising against these actions. Because the labeling directives in the prescribing information regarding product administration are adequate, we question if these errors may be attributable in part to the fact that the proprietary names of these products did not include a modifier in their proprietary name to signal to healthcare providers that the product is extended release or delayed release. Please include an assessment of this risk in your request for name review submitted to the NDA.

1 BACKGROUND

1.1 INTRODUCTION

The Sponsor, Osmotica Pharmaceuticals Inc., requested an assessment of the proposed proprietary name in a submission dated December 22, 2010.

1.2 REGULATORY HISTORY

Initially, the Applicant submitted the proposed proprietary name, (b) (4), for review. However, DMEPA informed the Sponsor via teleconference on December 21, 2010, that this name would be unacceptable because of its orthographic similarity to (b) (4). Hence, the Sponsor submitted the alternative name, Osmolex.

1.3 PRODUCT INFORMATION

Osmolex is the proposed proprietary name for Amantadine Extended-release Tablets. Osmolex has a proposed (b) (4). The recommended oral dose is a 160 mg to 320 mg once daily with or without food; the maximum daily dose is 320 mg per day. Osmolex tablets will be supplied in bottles and in unit-dose for institutional use and stored at controlled room temperature [20 ºC to 25ºC (68 ºF to 77ºF)]. Osmolex will be used in the home and hospital settings and will be dispensed through regular pharmacy distribution methods.

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 and 2.3 identify information associated with the methodology for the proposed proprietary name, Osmolex.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'O' 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 Osmolex, the DMEPA safety evaluators also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, capital letter O and lowercase l), down strokes (none), cross strokes (one, lower case 'x'), and dotted letters (none). Additionally, several letters in Osmolex 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 Osmolex.

When searching to identify potential names that may sound similar to Osmolex, the DMEPA safety evaluators search for names with similar number of syllables (three), stresses (OS-mo-lex, os-MO-lex, and os-mo-LEX), and placement of vowel and consonant sounds. The Sponsor's intended pronunciation (os´ moe lex) was also taken into consideration, as it was included in the Proprietary Name Review Request. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 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 medication orders and verbal prescriptions were communicated during the FDA prescription studies.

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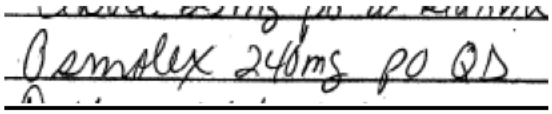
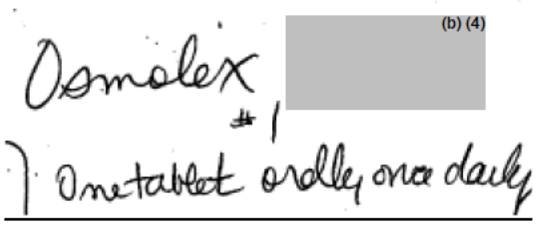
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

Figure 1. Osmolex Prescription Study (conducted on February 2, 2011)

WRITTEN MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: 	"Osmolex (b) (4) one tablet orally once daily #1"
Outpatient Prescription: 	

2.3 External Proprietary Name Risk Assessment

For this product, the Applicant 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 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 assessment differs, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

The names identified from DMEPA's methods as potential sources for name confusion with Osmolex are listed below.

3.1 DATABASE AND INFORMATION SOURCES

Our searches of database and DMEPA's information sources yielded a total of twenty-six names as having some similarity to the name Osmolex.

Fifteen of the names were thought to look like Osmolex. These included: Azelex, Arimidex, Ozurdex, Onsolis, Ornidex, Esmolol, Ocuflox, Osmoprep, Orlex, Enablex, Gamunex, Otomax HC, Oxalis, (b) (4)***, and Gentex LA. Two names (Esidrix and Mycelex) were thought to sound like Osmolex. The remaining nine names, Asmalix, Asmanex, Osmolex, Embolex, Osmovist, Casodex, Osmolite, Osmitrol, and Osmolax were thought to look and sound similar to Osmolex.

Additionally, DMEPA safety evaluators did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 5, 2011.

3.2 EXPERT PANEL DISCUSSION

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

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 PRESCRIPTION ANALYSIS STUDIES

A total of 39 practitioners responded to the prescription analysis study. The majority of responses for all the studies were correct (n=36). Incorrect responses were received in the inpatient study (n = 2) and the voice study (n = 1). Misinterpretations included mistaking the 'O' for an 'A' and the 'e' for an 'i' (both in the inpatient study) and misinterpreting the 's' for a 'z' (in the voice study). One response in the inpatient study, Asmolex, is similar in spelling to a currently marketed product Asmalix. The name, Asmalix, is evaluated in Appendix I.

3.4 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Sponsor, the (b) (4) found the name acceptable. (b) (4) identified and evaluated thirteen names (Asmalix, Asmanex, Casodex, Ismo, Myoflex, Omeprazole, Osmoglyn, Osmolite, Osmoprep, Osteo Bi-Flex, Sanorex, Sebulex, and Zanaflex) that were thought to have some look-alike and/or sound-alike qualities and potential for confusion with Osmolex. Five of the names (Asmalix, Asmanex, Casodex, Osmolite, and Osmoprep) were also identified by DMEPA during the database searches. Therefore, DMEPA added the remaining eight names to our analysis.

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

3.5 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

3.5.1 Initial Phase of Review

In response to a January 24, 2011 OSE e-mail, the Division of Neurology Products (DNP) indicated they had no objections to the proposed name, Osmolex.

3.5.2 Midpoint of Review (Carol, let me know when we can send this)

DMEPA notified DNP via e-mail that we had no concerns with the proposed proprietary name, Osmolex on June 14, 2011. Per e-mail correspondence from DNP on June 14, 2011, they noted no concerns with the proposed proprietary name, Osmolex.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary DMEPA safety evaluator resulted in the identification of one additional name, (b) (4) which was thought to look similar to Osmolex and represent a potential source of drug name confusion.

Thus, we identified in total, 35 names as having similarity to the proposed name.

4 DISCUSSION

This proposed name, Osmolex, 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 DNP concurred with the findings of DDMAC's promotional assessment of the proposed proprietary name.

4.2 SAFETY ASSESSMENT

The safety assessment considered the similarity of the proposed name to currently marketed products. We also considered the safety implications associated with the composition of this name, the absence of a modifier that designates this product is extended-release.

4.2.1 Sound-Alike and Look-Alike Assessment

Thirty-five names were identified for their potential similarity to the proposed name, Osmolex. Seventeen of the 35 names were eliminated for the reasons described in Appendices D through H. Appendix D lists eight proprietary names which lack sufficient orthographic and/or phonetic similarities with Osmolex to result in confusion. The name, Osmolex, was identified in our database search and is actually the name for this product under review. Since the trademark is licensed to the Sponsor of this application, it was eliminated from further analysis (see Appendix E). Appendix F describes five proprietary names for products that are unlikely to be confused with the proposed name, Osmolex, for the reasons stated, and Appendices G and H describe three names that are no longer marketed or have never been marketed in the United States.

Failure mode and effects analysis (FMEA) was 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 Osmolex and the 18 identified names was unlikely to result in medication error for the reasons presented in Appendix I.

4.2.2 The Absence of a Modifier for an Extended-release Dosage Form

As proposed, the Applicant does not include a modifier with the name (e.g., ER, XR, SR, CR) to convey that it is an extended release dosage form. Wrong technique errors (e.g., chewing, splitting, or crushing) of extended release tablets marketed under various proprietary names without extended-release modifiers have been previously identified in the Adverse Event Reporting System (AERS). DMEPA has described this issue in previous reviews (OSE 2006-879 dated March 8, 2007; OSE 2010-1134 dated February 25, 2011; and OSE 2011-207 dated April 19, 2011).

Specifically, there are several cases where patients split, crushed, or chewed tablets under the direction of a physician, despite the inclusion of statements in the product labeling advising that tablets are not to be split, crushed, or chewed. Because extended-release formulations frequently include modifiers within the brand name and the labeling directives in the prescribing information regarding product administration are adequate, we wonder if these errors are attributable in part to the fact that the proprietary names of these products did not include a modifier in their proprietary name to signal to healthcare providers that the product is extended release or delayed release.

Based on our post-marketing experience with other extended-release drug products with proprietary names that lack extended-release modifiers, we have some concern that the name Osmolex (without a modifier) may lead to maladministration errors. The Sponsor should address this risk with their next submission.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Osmolex, is not promotional. However, we have some concern that the name Osmolex without a modifier to convey that it is an extended release dosage form may lead to maladministration errors. We recommend the Sponsor include an assessment of this risk in their request for name review submitted to the NDA. The Sponsor will be notified of this finding via letter.

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.

If you have further questions or need clarifications, please contact Laurie Kelley, OSE Project Manager, at 301-796-5068.

5.1 COMMENTS TO THE SPONSOR

We have completed our review of this proposed proprietary name and have concluded that this name is acceptable from a promotional, sound and look-alike perspective. However, your proposed proprietary name lacks a modifier to convey the extended-release properties of the product (e.g., ER, XR, SR, and CR). Specifically, wrong technique errors (e.g., chewing, splitting, or crushing) with extended release tablets marketed under various proprietary names without modifiers have been previously identified in post marketing reporting. Many patients were instructed by their physician to crush, chew or split the tablet despite the inclusion of warning statements in the product labeling advising against these actions. Because the labeling directives in the prescribing information regarding product administration are adequate, we question if these errors may be attributable in part to the fact that the proprietary names of these products did not include a modifier in their proprietary name to signal to healthcare providers that

the product is extended release or delayed release. Please include an assessment of this risk in your request for name review submitted to the NDA. (See the Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names,* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Laurie Kelley, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5068. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Stacy Metz at (301) 796-2139.

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

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

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

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

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

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

7. 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)

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)

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)

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)

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/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.

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)

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

1 ***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. [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

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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.

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 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 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.

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

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

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

Lastly, 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.

1 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.

1 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?"***

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

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 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), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names 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).

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.

Appendix B: Potential orthographic or phonetic misinterpretation of the letters in the name Osmolex

Letters in Name, Osmolex	Scripted may appear as	Spoken may be interpreted as
Capital 'O'	Q, A	
lowercase 's'	g, 5, n	x, z
lowercase 'm'	rn, nn, n, v, w, wi, onc, z	n
lowercase 'o'	a, c, e, u	oh
lowercase 'l'	i, b, e	
lowercase 'e'	a, i, l, p	a, i
lowercase 'x'	f, k, p, t, y	

Appendix C: **FDA Prescription Study Responses for Osmolex (February 2, 2011)**

Study Name: Osmolex

82 People Received Study

39 People Responded

Study Name: Osmolex

INPATIENT	VOICE	OUTPATIENT
Asmolex (1)	Osmolex (9)	Osmolex (12)
Osmolex (8)	osmolex (2)	osmolex (3)
Osmolix (1)	ozmolex (1)	
osmolex (2)		

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

Proprietary Name	Similarity to Osmolex
Mycelex	Sound
Ismo (b) (4))	Look or Sound
Myoflex (b) (4)	Look or Sound
Omeprazole (b) (4)	Look or Sound
Sanorex (b) (4)	Look or Sound
Sebulex (b) (4)	Look or Sound
Zanaflex (b) (4)	Look or Sound
Osteo Bi-Flex (b) (4)	Look or Sound

Appendix E: Name which is the focus of this review.

Proprietary Name	Comments
Osmolex	USPTO

Appendix F: Drug name which is unlikely to be confused with Osmolex for the reasons described.

Proprietary Name	Similarity to Osmolex	Comments
Ornidex (L-Ornithine) 300 mg/2 capsules	Look	Ornidex is a product listed as a natural medicine and has been discontinued by the manufacturer (Source: Natural Medicines Database) and is not currently available through Redbook or online
Otomax – HC (benzalkonium, chloroxylenol, hydrocortisone, and pramoxine) Solution 15 mL	Look	Unable to define product characteristics after searching the following databases: Redbook, Drugs@FDA, Clinical Pharmacology, Facts % Comparisons, Lexi-Comp, and Rxlist.
Oxalis (Oxalic acid) also known as 'wood orrel' (source: Natural Medicines Database)	Look	A naturally occurring plant used for liver and digestive disorders, scurvy, wounds, and inflammation of the gums. There is no typical dosage. It is unlikely that this product would be prescribed in the traditional health care system.
Osmolite 33 fluid ounces to 50 fluid ounces	Look and Sound	Source of nutrition for long-term tube feeding; prescribers are likely to order in XX mL per dose to meet individual patient needs
Osmoglyn (Glycerin) 50% Solution (b) (4))	Look or Sound	Per Clinical Pharmacology, this product is no longer in the marketplace. (Name not found in Drugs@FDA, Facts & Comparisons, Redbook, or Lexi-Comp.)

Appendix G: Drug name which is no longer marketed in the US and has no therapeutic equivalents.

Proprietary Name	Comments
Osmovist 190 (Iotrolan) Injection 40.6% Osmovist 240 (Iotrolan) Injection 51.3%	Applicant requested withdrawal of this application (NDA 019580) effective June 10, 1999 (Source: DARRTS)
Embolex (Dihydroergotamine Mesylate and Heparin Sodium and Lidocaine Hydrochloride) Injection 0.5 mg/0.5 mL; 2,500 units/0.5 mL; 5.33 mg/0.5 mL	NDA 018885 withdrawn by the Applicant effective March 20, 1992 (Source: DARRTS)

Appendix H: Drug names not marketed in the U.S.

Proprietary Name	Similarity to Osmolex	Comments
(b) (4) ***(Glycopyrrolate) Oral Solution 1 mg/5 mL Usual dose: Initiated at (b) (4) 0.02 mg/kg three times daily	Look	DMEPA objected to this name (OSE 2010-37 dated March 9, 2010, NDA 022571) based upon its similarity to the marketed names, Azilect and Acyclovir. The alternative name submitted and approved July 28, 2010 was 'Cuvposa'. Therefore, the name, (b) (4) is considered dead.

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

Appendix I: Potentially confusing names with orthographic and/or phonetic differences and differentiating product characteristics that decrease the risk of medication errors.

Failure Mode: Name confusion	**Reasons for the potential failure mode (could be multiple)**	**Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.**
Proposed name and strength **Osmolex (Amantadine) Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Azelex (Azelaic Acid) Cream 20% *Usual dose*: Apply to the affected area(s) two times daily	Orthographic similarity results from the similar appearance of their first letters ('O' vs. 'A') in some handwriting samples and sharing the same last three letters ('-lex') in their names.	The marketed name, Azelex, is shorter than the proposed name, Osmolex, when written giving these names slightly different lengths. Additionally, the letters which appear between the 'A' and 'l' (in Azelex) do not look orthographically similar to the letters which appear between 'O' and 'l' (in Osmolex). (For example, 'ze' does not look like 'smo' when scripted.) This feature may differentiate them from each other. Differences in product characteristics include strength (20% vs. (b) (4), 160 mg, 240 mg, and 320 mg), route of administration (topical vs. oral), and frequency of administration. Osmolex is available in more than one strength and therefore this information will need to be provided on a prescription to dispense/administer the drug as intended.
Arimidex (Anastrazole)Tablet 1 mg *Usual dose:* Take one tablet orally daily	Orthographic similarity results from the similar appearance of their first letters ('O' vs. 'A') in some handwriting samples and sharing the same last two letters ('-ex') in their names. Overlapping product characteristics include dosage form (tablet), route of administration (oral), and frequency of administration (once daily).	The letters between 'A' and the first up stroke ('rimi') in Arimidex do not look like the letters between 'O' and the first up stroke ('smo') in Osmolex when written. This difference may help to differentiate these names. One differing product characteristic is the strength (1 mg vs. (b) (4) 160 mg, 240 mg, and 320 mg). Osmolex is available in more than one strength and therefore this information will need to be provided on a prescription to dispense/administer these drugs as intended.

Failure Mode: Name confusion	Reasons for the potential failure mode (could be multiple)	Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.
Proposed name and strength **Osmolex (Amantadine)** **Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Ozurdex (Dexamethasone) Intravitreal Implant 0.7 mg Usual dose: Place into eye as directed.	Orthographic similarity stems from sharing the same first letter ('O'), having a single up stroke ('d' vs. 'l') and ending in the same two letters ('ex').	The letters between 'O' and the first up stroke ('zur') in Ozurdex do not look like the letters between 'O' and the first up stroke ('smo') in Osmolex when written. This difference may help to differentiate these names. Differing product characteristics include dose (0.7 mg vs. 160 mg, 240 mg, and 320 mg), route of administration (intravitreal vs. oral), and frequency of administration (one time vs. once daily). Osmolex is available in more than one strength which has to be specified by the prescriber prior to dispensing/administering this drug product.
Onsolis (Fentanyl Citrate) Buccal Film 200 mcg, 400 mg, 600 mcg, 800 mcg, and 1200 mcg Usual dose: Titrate using 200 mcg increments (up to a maximum of four 200 mcg films or a single 1200 mcg film) to adequate analgesia without undue side effects	Orthographic similarity stems form sharing the same first letter ('O') and having the same letter combination in the fourth and fifth positions ('-ol-') within their names. (b) (4)	The letters between 'O' and the first up stroke, ('-nso-'), in Onsolis do not look like the letters between 'O' and the first up stroke, ('-smo-') of Osmolex when written. Additionally, the terminal letters ('is' vs. 'ex') do not look similar when written. This difference may help to differentiate these names. Differing product characteristics include dose (200 mcg, 400 mcg, 600 mcg, 800 mcg, and 1200 mcg vs. 160 mg, 240 mg, and 320 mg), route of administration (intravitreal vs. oral), and frequency of administration (non-specified vs. once daily). Osmolex and Onsolis are available in more than one strength which has to be specified by the prescriber prior to dispensing/administering either drug product.

Failure Mode: Name confusion	**Reasons for the potential failure mode (could be multiple)**	**Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.**
Proposed name and strength **Osmolex (Amantadine)** **Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Esmolol Injection 10 mg/mL Usual dose: 50 mcg/kg/minute to 300 mcg/kg/minute	Orthographic similarity stems from the similar appearance of their first letters ('E' vs. 'O') in some handwriting samples and the fact that their second through fifth letters are the same ('-smol-').	The presence of the terminal up stroke ('l') in the marketed name, Esmolol, gives this name a different shape and may help to distinguish it from the proposed name, Osmolex. Differing product characteristics include dose (50 mcg/kg/ minute to 300 mcg/kg/minute vs. (b) (4), 160 mg, 240 mg, and 320 mg), route of administration (intravenous vs. oral), and frequency of administration (continuous vs. once daily). Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.
Ocuflox (Ofloxacin) ophthalmic solution 0.3% Usual dose: One to two drops in the affected eye(s) every 2 hours to 4 hours for 2 days, then one to two drops four times daily for 5 days	Orthographic similarity stems from sharing the same first and last letters ('O' and 'x') in their names.	The marketed name, Ocuflox, includes two sequential up strokes ('fl') which give this name a different shape and may differentiate this name from the proposed name, Osmolex. Differing product characteristics include dose (one drop to two drops vs (b) (4), 160 mg, 240 mg, or 320 mg), route of administration (eye vs. oral), and frequency of administration (every 2 hours to 4 hours or four times daily vs. once daily). Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.

Failure Mode: Name confusion	Reasons for the potential failure mode (could be multiple)	Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.
Proposed name and strength **Osmolex (Amantadine) Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Osmoprep (Sodium Phosphate, dibasic and Sodium Phosphate, monobasic) Tablet 0.398 grams/1.102 grams Usual dose: Four tablets every 15 minutes for a total of 20 tablets the evening before the colonoscopy, then on the day of the colonoscopy take 4 tablets orally every 15 minutes for a total of 12 tablets; MUST split dose regimen as recommended.	Orthographic similarity stems from sharing the same first through fourth letters (Osmo-) in their names. Overlapping product characteristics include dosage form (tablet) and route of administration (oral).	The marketed name, Osmoprep, includes two down strokes (two lower case 'p's) in its suffix which gives this name a different shape from the proposed name, Osmolex. Differing product characteristics include the dose (4 tablets) and the frequency of administration (every 15 minutes up to 20 tablets/12 tablets versus once daily) Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.
Orlex (Acetic Acid, Glacial) Solution/Drops, Otic 2% Usual dose: Instill 4 to 6 drops into the external auditory canal and maintain this position for 5 minutes. Repeat the procedure every 2 to 3 hours.	Orthographic similarity stems from sharing the same first letter ('O') and the last three letters ('-lex') of their names.	The marketed name, Orlex, is five letters in length versus the proposed name, Osmolex, which contains seven letters. Althuogh there is only a difference of three letters, the name Orlex appears significantly shorter when written. Differing product characteristics include the dose (4 to 6 drops vs (b) (4), 160 mg, 240 mg, and 320 mg), route of administration (otic vs. oral), and frequency of administration (every 2 to 3 hours vs. once daily). Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.

Failure Mode: Name confusion	Reasons for the potential failure mode (could be multiple)	Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.
Proposed name and strength **Osmolex (Amantadine)** **Extended-release tablet** **(b) (4) 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Enablex (Darifenacin) Extended-release tablet 7.5 mg, 15 mg Usual dose: 7.5 mg to 15 mg once daily	Orthogarphic similarity stems from the similar appearance of their first letters ('E' vs. 'O') in some handwriting samples and the fact that they share the last three letters ('lex'). Overlapping product characteristics include dosage form (Extended-release tablet), route of administration (oral), and frequency of administration (once daily)	The marketed name, Enablex, contains two consecutive up strokes ('b' and 'l') which gives this name a different shape from that of the proposed name, Osmolex. This difference may help to distinguish these names from each other. One differing product characteristic is the dose (7.5 mg, 15 mg, vs. (b) (4), 160 mg, 240 mg, 320 mg). Osmolex and Enablex are available in more than one strength and, therefore, this information would have to be specified to dispense/administer either medication as intended.
Gamunex (Immune Globulin) Injection 100 mg/mL Usual dose : 400 mg/kg intravenously once daily for 5 days or 1000 mg/kg intravenously for once daily for 2 days.	Orthographic similarity stems from the similar appearance of their first letters ('G' vs. 'O') and the fact that they share the same last three letters ('lex'). An overlapping product characteristic is their frequency of administration (once daily).	The marketed name, Gamunex, lacks an up stroke which is present in the proposed name, Osmolex (lower case 'l'). This feature gives these names different shapes and may help distinguish them from each other. Differing product characteristics include dose (400 mg/kg vs (b) (4), 160 mg, 240 mg, or 320 mg) and route of administration (intravenous vs. oral). Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.

Failure Mode: Name confusion	Reasons for the potential failure mode (could be multiple)	Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.
Proposed name and strength **Osmolex (Amantadine) Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Gentex LA (Guaifenesin and Phenylephrine) Extended-release Tablet 650 mg/23.75 mg Usual dose: One tablet every 12 hours	Orthographic similarity stems from the similar appearance of their first letters ('G' vs. 'O') in some handwriting samples, the fact that they have the same up stroke ('l') in similar positions within their name, and both names contain the same last two letters ('-ex'). Overlapping product characteristics include dosage form (Extended-release tablet) and route of administration (oral)	The marketed name, Gentex, includes a modifier, LA, which makes this name appear to be longer than the proposed name, Osmolex, when written. Since there are other products with the root name 'Gentex' but none that do not include a modifier, the prescriber would have to indicate this information in order to dispense/prescribe the product as intended. Differing product characteristics include dose (one tablet vs. (b) (4) 160 mg, 240 mg, or 320 mg) and frequency of administration (every 12 hours vs. once daily). Osmolex is available in several strengths and this information would have to be specified to dispense/administer the medication as intended.
Esidrix (Hydrochlorothiazide) Tablet 25 mg, 50 mg The name, Esidrix, has been discontinued, but generic products exist. Usual dose: 25 mg to 100 mg per day in single or divided doses	Orthographic similarity stems from the similar appearance of their first letters ('E' vs. 'O') in some handwriting samples, the fact that both names have a single up stroke ('d' vs. 'l'), and they both end with a cross stroke ('x'). Overlapping product characteristics include dosage form (tablet), route of administration (oral), and potentially frequency of administration (once daily)	The space between the first letter ('E' and 'O' and the up stroke ('d' and 'l') is longer in the proposed name, Osmolex and the marketed name, Esidrix. This is because of the number of letters (two vs. three) as well as their appearance 'si' vs. 'smo'. This difference may help to differentiate these names. One different product characteristic includes dose (25 mg, 50 mg vs. (b) (4) 160 mg, 240 mg, 320 mg). Osmolex and Esidrix are available in more than one strength and, therefore, this information would have to be specified to dispense/administer either medication as intended.

Failure Mode: Name confusion	Reasons for the potential failure mode (could be multiple)	Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.
Proposed name and strength **Osmolex (Amantadine) Extended-release tablet** **(b) (4), 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Asmanex (Mometasone) Twisthaler 0.22 mg/inhalation, 0.11 mg/inhalation Usual dose: 220 mcg (one puff) to 440 mcg (2 puffs) once daily to twice daily (maximum recommended is 880 mcg)	Orthographic similarity results from the similar appearance of their first letters ('O' vs. 'A') in some handwriting samples and the fact that they share two letter combinations in their names ('-sm-' and '-ex'). Phonetic similarity stems from having three syllables and sharing two letter combinations in their names ('-sm-' and '-ex'). Overlapping product characteristics include route of administration (oral) and frequency of administration (once daily)	The marketed name, Asmanex, includes the modifier, Twisthaler, which makes this name longer than the proposed name, Osmolex, when written. Additionally, the name, Osmolex contains a single up stroke ('l') which makes this name a different shape from the name, Asmanex. These features may help to differentiate these names from each other. One differing product characteristics is the dose (1 puff or 2 puffs vs. (b) (4) 160 mg, 240 mg, or 320 mg). Osmolex and Asmanex are available in more than one strength and, therefore, this information would have to be specified to dispense/administer either medication as intended.
Casodex (Bicalutamide) Tablet 50 mg Usual dose: One tablet orally once daily	Orthographic similarity stems from the similar appearance of their first letters ('C' vs. 'O') in some handwriting samples as well as the fact that both names have one up stroke in the same location and end with the same letters ('-ex'). Phonetic similarity	The letters between 'C' and the first up stroke, ('-aso-'), in Casodex do not look like the letters between 'O' and the first up stroke, ('-smo-') of Osmolex when written. This difference may help to differentiate these names. One differing product characteristics includes strength (50 mg vs. (b) (4) 160 mg, 240 mg, and 320 mg). Osmolex is available in more than one strength which has to be specified by the

	stems from both names having three syllables and sharing three letters letters in the same locations within their names ('o', 'e', and 'x'). Overlapping product characteristics include dosage form (tablet), route of administration (oral) and frequency of administration (once daily).	prescriber prior to dispensing/administering either drug product.

Failure Mode: Name confusion	**Reasons for the potential failure mode (could be multiple)**	**Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.**
Proposed name and strength **Osmolex (Amantadine)** **Extended-release tablet** **(b) (4) 160 mg, 240 mg, 320 mg**		**Usual dose:** **160 mg to 320 mg once daily**
Osmitrol (Mannitol) Intravenous Solution 5%, 10%, 15%, 20% Usual dose: 50 grams to 100 grams intravenously as a 5% to 20% solution during surgery, postoperatively or following trauma	Orthographic similarity stems from sharing the same first three letters (Osm) and having one up stroke ('t' and 'l') in the same position within their names. Phonetic similarity stems from the fact that both names have three syllables and share the first three letters ('Osm-') of their names.	The marketed name, Osmitrol, includes a terminal up stroke ('l') which gives this name a different shape from that of the proposed name, Osmolex. This feature may help to differentiate between this name pair. Differing product characteristics include dose (50 grams to 100 grams vs. (b) (4), 160 mg, 240 mg, or 320 mg), route of administration (intravenous vs. oral), and frequency of administration (one time vs. once daily). Osmolex and Osmitrol are available in more than one strength and, therefore, this information would have to be specified to dispense/administer either medication as intended.
Asmalix (Theophylline) Oral solution 80 mg/15 mL Brand name discontinued, but generics exist in the marketplace Usual dose: 12 mg/kg to 18 mg/kg given 2 to 4	Orthographic similarity stems from the similar appearance of their first letters ('O' and 'A'), the fact that these names share four out of seven letters within their names ('s', 'm', 'l', and 'x').	One differing product characteristic is frequency of administration (2 to 4 times daily vs. once daily). Osmolex is available in more than one strength which has to be specified by the prescriber prior to dispensing/administering either drug product. Additionally, prescriber is likely to indicate the units of measurement

times daily	Phonetic similarity stems from both names having three syllables and sharing four out of seven letters ('s', 'm', 'l', and 'x'). Overlapping product characteristics include [redacted] and route of administration (oral).	as 'milliliters' (of Asmalix) if the solution is desired. ***Preliminary drug usage data suggests that there is no opportunity for confusion between the marketed name, Asmalix and the proposed name, Osmolex.***

Failure Mode: Name confusion	**Reasons for the potential failure mode (could be multiple)**	**Rationale for why confusion is unlikely to occur between the proposed name and the marketed name.**
Proposed name and strength Osmolex (Amantadine) Extended-release tablet [redacted], 160 mg, 240 mg, 320 mg		**Usual dose: 160 mg to 320 mg once daily**
Osmolax (Lactulose) Solution 3.4 grams/5 mL Usual dose: 15 mL twice daily	Orthographic and phonetic stem from sharing six out of seven letters in their name. Overlapping product characteristics include route of administration (oral).	Differing product characteristics include dose (15 mL vs. [redacted] 160 mg, 240 mg, or 320 mg), and frequency of administration (twice daily vs. once daily). Osmolex is available in more than one strength which has to be specified by the prescriber prior to dispensing/administering either drug product. ***Preliminary drug usage data suggests that there is no opportunity for confusion between the marketed name, Asmalix and the proposed name, Osmolex.***
[redacted]***(Secukinumab) for Injection 150 mg/vial Usual dose: 300 mg subcutaneously either every 2 weeks or monthly	Orthographic similarity [redacted]	[redacted] Differing product characteristics include dose (300 mg vs [redacted], 160 mg, 240 mg, or 320 mg), route of administration (subcutaneous vs. oral), and frequency of administration (every

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

		2 weeks or monthly vs. once daily). Osmolex is available in more than one strength which has to be specified by the prescriber prior to dispensing/administering either drug product.

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/s/

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