CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	October 10, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Oxtellar XR (Oxcarbazepine) Extended-release Tablets 150 mg, 300 mg, 600 mg
Application Type/Number:	NDA 202810
Applicant/Sponsor:	Supernus Pharmaceuticals
OSE RCM #:	2012-2021

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

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Oxtellar XR, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

This NDA is a 505(b)(2) application. The Reference Listed Drugs (RLD) are Trileptal Oral Tablets and Trileptal Oral Suspension.

The Applicant initially submitted the proposed proprietary name (b) (4) for this product on March 31, 2009 under IND 077417. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name (b) (4) acceptable in OSE Review # 2009-1012. However, because the Applicant thought the proprietary name (b) (4) was too similar to the newly approved product (b) (4), the Applicant decided to submit a different proprietary name under the NDA.

The Applicant subsequently submitted the proposed proprietary name (b) (4) on February 8, 2012 under the NDA. DMEPA found the proposed proprietary name (b) (4) unacceptable in OSE Review # 2012-373 dated May 3, 2012 due to orthographic similarity and overlapping product characteristics with (b) (4).

The Applicant submitted the proposed proprietary name (b) (4) on July 3, 2012. From a safety perspective, the proposed proprietary name (b) (4) is vulnerable to confusion with the established name, (b) (4) which was adopted by the United States Adopted Name (USAN) Council and the International Nonproprietary name (INN). From a promotional perspective, the proposed proprietary name (b) (4) misleadingly minimizes the potential risks associated with the drug. DMEPA and the Office of Prescription Drug Promotion (OPDP) communicated these concerns to the Applicant in a teleconference on August 8, 2012. The Applicant withdrew the name (b) (4) on August 9, 2012. The Applicant submitted the proposed proprietary name under review, Oxtellar XR, on August 29, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 29, 2012 proprietary name submission.

Active Ingredient: Oxcarbazepine

Indication of Use: Adjunctive therapy in the treatment of partial seizures in adults and children aged (b) (4) to 17 years old

Route of administration: Oral

Dosage form: Extended-release Tablets

Strength: 150 mg, 300 mg, and 600 mg

Dose and Frequency of Administration:

Adults: Initiate with a dose of 600 mg/day; given once daily. The dose may be increased by a maximum of 600 mg/day at approximately weekly intervals. The recommended daily dose is between 1,200 mg to 2,400 mg per day.

Children: 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily.

Patients with Renal Impairment: In patients with impaired renal function (creatinine clearance less than 30 mL/min), therapy should be initiated at one-half the usual starting dose (300 mg per day) and increased slowly to achieve the desired clinical response.

How Supplied: 100-count bottles and 5-count professional sample blister cards

Storage: 25ºC (77ºF); excursions permitted between 15ºC and 30ºC (59ºF to 86ºF)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The September 21, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name contains two components: 1) the proposed root name, Oxtellar, and 2) a modifier XR. In the proprietary name submission, the Applicant stated the root name "Oxtellar" is not derived from any one particular concept, although the name contains the INN stem "ox." "Ox" is not used in the stem position and therefore does not risk regulatory rejection due to the use of the stem. Also, the stem "ox" does not appear in the list of defined USAN stems. We have evaluated whether the proposed modifier "XR" is appropriate to signal the extended-release nature of this product (see Failure Mode and Effects Analysis of the Modifier).

2.2.3 FDA Name Simulation Studies

One hundred and one (n=101) practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. In the verbal studies, the first and second syllable 'oxtell' were misheard as 'oxstell' and 'oxstel.' The letter 'a' in Oxtellar XR was misinterpreted as the letter 'o' in the written studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, September 6, 2012 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

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

Table 1: Collective List of Potentially Similar Names (EPD and PR)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Ophthaine	EPD	Extraneal	EPD	Otitricin	EPD
Proklar	EPD	(b) (4)	PR	Vetalar	PR
Optulle	PR	(b) (4)	PR	(b) (4)	PR
(b) (4)	PR	Opti-Clean II	EPD	Otic Care	EPD
Opti-Lean	PR	Cystellin	PR	Oxytocin	EPD
Acular LS	EPD	Aptivus	EPD	Astelin	EPD
Cytotec	PR	Ostera	PR	Opti-Clear	EPD
OptiFlex-G	EPD	OptiFlex-C	PR	Celontin	PR
Ovrette	EPD	Oxacillin	EPD	Antiben	PR
(b) (4) ***	PR	Cefaclor	PR	Ketalar	EPD
Cytadren	PR	Oxytrol	EPD	Epiflur	PR
Cataflam	PR	Optivar	EPD	[redacted]	[redacted]

Table 1: Collective List of Potentially Similar Names (EPD and PR)					
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
(b) (4) ***	EPD	Ocella	EPD	[redacted]	[redacted]
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Oxecta	EPD	(b) (4)	PR	Activella	EPD

Our analysis of the 40 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all forty names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Neurology Products via e-mail on September 14, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products on September 24, 2012, they stated no additional concerns with the proposed proprietary name, Oxtellar XR.

3 DISCUSSION

The proposed proprietary name, Oxtellar XR, includes the modifier "XR" to convey its extended-release properties. Although there is no marketed immediate release oxcarbazepine product with the root name, Oxtellar, there are immediate-release oxcarbazepine tablets and oral suspensions currently marketed by another firm under the proprietary name Trileptal as well as multiple generic products marketed under the established name, oxcarbazepine. If approved, Oxtellar XR will be the first extended-release oxcarbazepine formulation on the market.

Trileptal is an immediate release film-coated tablet available in 150 mg, 300 mg, and 600 mg strengths. All three strengths are scored tablets which facilitate splitting of the tablets. Trileptal oral suspension is available in a 300 mg per 5 mL strength. All dosing for Trileptal should be given in a twice-a-day regimen. Trileptal oral suspension and Trileptal film-coated tablets may be interchanged at equal doses. The proposed product, Oxtellar XR, is an extended-release tablet that is administered once daily. Oxtellar XR should be swallowed whole and should not be cut, crushed or chewed.

The Applicant, Supernus Pharmaceuticals, does not currently market an immediate-release formulation of Oxtellar that this extended-release formulation needs to distinguish itself from. Thus, in light of that fact, we evaluated whether or not a modifier is necessary for this product to signal the extended-release nature of the product. We also evaluated whether the lack of a modifier raises a potential safety concern, given the overlapping product characteristics of this product to the currently marketed immediate-release formulations.

First, we identified extended-release products approved without a modifier in the proprietary name and reviewed documented errors relating to wrong technique and wrong frequency of administration. Wrong technique errors involved patients or practitioners, chewing, splitting, opening, or crushing the extended-release oral dosage forms when these products were intended to be administered intact. Wrong frequency errors involved the administration of the extended-release dosage form at intervals more frequent than labeled, (e.g. taking a once daily drug twice a day). Wrong technique and wrong frequency errors occurred despite the presence of clear labeling directives to administer the products intact and at the given intervals. Additionally, based on the case narratives we were unable to determine a definitive root cause of the errors. These reports included extended-release products that had overlapping product strengths with immediate-release formulations.

We then considered whether the lack of a modifier may actually contribute to practitioners' and patients' knowledge deficit about the extended-release properties of the drug products. As it relates to this product, this consideration led us to evaluate whether the addition of a modifier to the Oxtellar name might help to avoid some of the wrong technique and wrong frequency errors.

With respect to wrong technique errors, we reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms that Should Not be Crushed" to determine if a modifier exists that conveys an extended-release dosage form should not be divided, cut, crushed, or chewed. We focused our review on those names with modifiers that are commonly used to denote extended-release (eg., ER, SR, CR, XR, XL, and LA), since the Institute of Medicine has charged the FDA and Industry to standardize abbreviations to the greatest extent possible. Our review found this list contains a nearly equal number of extended-release drug products in which the proprietary name contains a modifier (n=82) to extended-release products with drug names without modifiers (n=84). Based on this information, we conclude there is no standard single modifier currently in the market today that is definitively linked to the requirement that an extended-release product should not be manipulated prior to administration. Although a clear pattern did not emerge from our review of this list with modifiers, our medication error postmarketing experience with drug products marketed without a modifier in the proprietary name leads us to believe that the failure to include a modifier that conveys the extended-release properties of the drug may predispose the product to wrong technique and wrong frequency errors. Therefore, in some circumstances, a modifier in the proprietary name of an extended-release product may help reduce the risk of these types of errors.

In this circumstance, Oxtellar XR has direct overlapping strengths with the currently marketed immediate-release oxcarbazepine tablets (150 mg, 300 mg and 600 mg). Additionally, we note Trileptal tablets are scored to facilitate splitting of the tablets. Since Oxtellar XR is an extended-release tablet that should be swallowed whole and not cut, crushed, or chewed, we determined the modifier may signal to healthcare practitioners that Oxtellar XR differs from the currently marketed immediate-release oxcarbazepine formulations on the market. The presence of the modifier may trigger healthcare providers to consult the full prescribing information to determine how Oxtellar XR should be administered. We recognize there are limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked;

however, given the risks associated with confusing Oxtellar XR with the immediate release products, we believe the modifier adds an incremental measure of safety.

As previously noted, the Applicant selected the modifier "XR" for this product in order to signal the extended-release properties of their drug. Although "XR" has been used to communicate once or twice daily administration, most products with the XR modifier are dosed once daily and the modifier "XR" has not been cited as a source of confusion postmarketing. Therefore, the use of the modifier "XR", in this circumstance, is consistent with the majority of other XR products that are currently marketed.

Postmarketing surveillance of medication errors has identified wrong drug errors that involve products with the same active ingredient and overlapping product characteristics, but different release mechanisms. Ideally, we recommend avoiding overlaps in strength for drug products that have the same active ingredient, but different formulations. However, since strength modification is not feasible at this point in product development, the nomenclature and labels and labeling of this product might help to communicate the product's extended-release properties and minimize the risk for medication errors.

Given the totality of factors considered above, we conclude the proposed modifier, "XR", is appropriate for this product.

4 CONCLUSIONS

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

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

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Oxtellar XR, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your August 29, 2012 submission are altered, the name must be resubmitted for review.

5 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)***

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

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

10. ***Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

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

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Oxtellar XR	Scripted May Appear as	Spoken May Be Interpreted as
Upper case O	Q	Oh
Lower case o	a, c, e, u	oh
Lower case x	a, d, f, k, n, p, r, t, v, y, z	ks, kz, s, z
Lower case t	f, l, r, x	d
Lower case e	a, c, i, l, p, o, r, u	
Lower case l	b, c, e, i, s, t	
Lower case a	ci, cl, d, o, u, e	e, i, o, u
Lower case r	c, e, n, s, v	wr
Upper case X	K, P, U, V, Y	S, Z
Upper case R	B, Pr, K	Wr

Appendix C: Prescription Simulation Samples and Results

Figure 1. Study (Conducted on September 7, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Oxtellar XR 600mg po once daily	Oxtellar XR 600 mg Three tablets by mouth once daily # 90
Outpatient Prescription: Oxtellar XR 600 mg 3 tabs. po once daily	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study

101 People Responded

Total	32	32	37	
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
OCSTALLAR	0	1	0	1
OSTELLAR XR	0	1	0	1
OXELLAR XR	1	0	0	1
OXSTELAR XR	0	1	0	1
OXSTELER XR	0	1	0	1
OXSTELLAR SR	0	1	0	1
OXSTELLAR XR	0	7	0	7
OXSTELLER XR	0	1	0	1
OXTELAR	1	0	0	1
OXTELAR XR	0	4	0	4
OXTELER XR	0	2	0	2
OXTELLAR	2	0	1	3
OXTELLAR SR	0	1	0	1
OXTELLAR XR	24	6	34	64
OXTELLAR XR 600MG	0	0	1	1
OXTELLAR-XR	0	1	0	1
OXTELLER SR	0	1	0	1
OXTELLER XR	0	3	0	3
OXTELLOR XR	3	1	0	4
OXTELLOT XR	1	0	0	1
QXTELLAR XR	0	0	1	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Oxtellar XR	Failure preventions
1.	(b) (4) ***	(b) (4)	Sound-alike	(b) (4) *** was not reviewed by DMEPA since the Sponsor withdrew the IND application.
2.	Ophthaine	Proparacaine	Look-alike	The pair have sufficient orthographic differences.
3.	Proklar	Sulfamethizole	Look-alike	The pair have sufficient orthographic differences.
4.	Extraneal	Icodextrin	Look-alike	The pair have sufficient orthographic differences.
5.	Otic Care	Antipyrine, Benzocaine, and Polycosanol	Look-alike	The pair have sufficient orthographic differences.
6.	Otitricin	Hydrocortisone, Neomycin, and Polymyxin B	Look-alike	The pair have sufficient orthographic differences.
7.	Cataflam	Diclofenac	Look-alike	The pair have sufficient orthographic differences.
8.	Oxytocin		Look-alike	The pair have sufficient orthographic differences.
9.	Oxytrol	Oxybutynin	Look-alike	The pair have sufficient orthographic differences.
10.	Oxecta	Oxycodone	Sound-alike and look alike	The pair have sufficient phonetic and orthographic differences.
11.	(b) (4)	Azelastine	Look-alike	Proposed Proprietary Names found unacceptable by DMEPA (OSE Review # 2007-1920 and 2007-1911). Product approved under new proprietary name Astepro.

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

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.				
12.	(b) (4) ***	Carbidopa, Levodopa, and Entacapone	Look-alike	Proposed Proprietary Name found unacceptable by DMEPA (OSE Review # 02-0020). Product approved under the proprietary names Stalevo 50, Stalevo 75, Stalevo 100, Stalevo 125, Stalevo 150, and Stalevo 200.
13.	(b) (4) ***	Ketoprofen	Look-alike	Proposed Proprietary Name found unacceptable by DMEPA (OSE Review # 2009-194). Product approved under the proprietary name Nexcede.
14.	(b) (4) ***	Rilpivirine	Look-alike	Proposed Proprietary Name was not formally submitted for review. Product approved under the proprietary name Edurant.
15.	Opti-Lean	Garcinia Cambogia, Protein, Carbohydrates	Look-alike	Name identified in the Natural Medicines database. Unable to find product characteristics in commonly used drug databases.
16.	Cytellin	Sistosterols	Look-alike	Name identified in the DARRTS database. Unable to find product characteristics in commonly used drug databases.

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Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Activella (Estradiol and Norethindrone) Tablets <u>Strength:</u> Estradiol 0.5 mg and Norethindrone 0.1 mg; Estradiol 1 mg and Norethindrone 0.5 mg <u>Dosage:</u> One tablet by mouth once daily	<u>Orthographic:</u> The first letter 'A' and 'O' look similar when scripted. Both names contain a cross stroke letter t at the third position and the letter string 'ella' in the infix and suffix. <u>Dosage and dosage form:</u> Both products may be prescribed as 'Take one tablet' <u>Frequency of administration:</u> Both products are administered once daily. <u>Route of administration:</u> Both products are administered orally.	<u>Orthographic:</u> The letter 'c' in Activella and the letter 'x' in Oxtellar XR look different when scripted. Activella contains three letters between the cross stroke letter 't' and the double upstroke letter pair 'll' vs. Oxtellar XR contains only one letter between the cross stroke letter 't' and the double upstroke letter pair 'll.' If written, the modifier 'XR' would differentiate Oxtellar XR from Activella. <u>Phonetic:</u> Activella contains four syllables vs. Oxtellar XR contains three syllables. The syllables in both names sound different when spoken. <u>Strength:</u> Since both products are available in multiple strengths, a strength would need to be specified on a prescription. The strengths of the two products do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2.	Acular LS (Ketorolac) Solution <u>Strength:</u> 0.4 % <u>Dosage:</u> One drop into affected eye(s) four times daily as needed	<u>Orthographic:</u> The first letter 'A' and 'O' look similar when scripted. Both names contain the letter string 'lar' in the suffix and contain a modifier.	<u>Orthographic:</u> Acular LS contains six letters vs. Oxtellar XR contains eight letters. The letter 'c' in Acular LS and the letter 'x' in Oxtellar XR look different when scripted. Acular LS does not contain a cross stroke letter at the third position vs. Oxtellar XR contains a cross stroke letter at the third position. Acular LS contains an upstroke letter 'l' at the fifth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth and sixth position. The modifier LS and XR look different when scripted. <u>Strength:</u> Since Acular LS is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Acular LS.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Aptivus (Tipranavir) Capsules and Solution Strength: 250 mg Capsules; 100 mg per mL Solution Dosage: 500 mg by mouth twice daily; 14 mg/kg or 375 mg/m^2 by mouth twice daily in pediatrics	Orthographic: The first letter 'A' and 'O' look similar when scripted. The letter 'p' in Aptivus and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in Aptivus and the letter 'e' in Oxtellar XR look similar when scripted. The letter pair 'us' in Aptivus and 'ar' in Oxtellar XR look similar when scripted. Dosage: Since the pediatric dosage for Aptivus is individualized to a patient's weight, there is potential overlap in dosage: Aptivus 300 mg and Oxtellar XR 300 mg Route of administration: Both products are administered orally.	Orthographic: Aptivus does not contain an upstroke letter at the fifth or sixth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth and sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Aptivus.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
4.	Astelin (Azelastine) solution <u>Strength:</u> 127 mcg per actuation <u>Dosage:</u> One to two sprays per nostril twice daily	<u>Orthographic:</u> The first letter 'A' and 'O' look similar when scripted. The letter 's' in Astelin and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain the letter string 'tel' starting at the third position. The letter pair 'in' in Astelin and the letter pair 'ar' in Oxtellar XR look similar when scripted.	<u>Orthographic:</u> Astelin contains an upstroke letter 'l' at the fifth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth and sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Astelin. <u>Strength:</u> Since Astelin is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Astelin.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5.	Ketalar (Ketamine) Injection <u>Strength:</u> 10 mg per mL; 50 mg per mL; 100 mg per mL <u>Dosage:</u> 0.5 mg/kg to 4.5 mg/kg intravenously; 0.5 mg/kg/min intravenously with diazepam induction; 0.1 mg/min to 0.5 mg/minute intravenously with diazepam maintenance; 3.25 mg/kg to 13 mg/kg intramuscularly	<u>Orthographic:</u> Both names contain a cross stroke letter 't' at the third position. The letter 'a' at the fourth position of Ketalar and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain the letter string 'lar' in the suffix. <u>Dosage:</u> Since the dosage for Ketalar has a wide range and is individualized to patient's weight, there is potential for overlap in dosage: Ketalar 300 mg vs. Oxtellar XR 300 mg	<u>Orthographic:</u> The first letter 'K' and 'O' look different when scripted. The letter 'e' in Ketalar and the letter 'x' in Oxtellar XR look different when scripted. Ketalar contains an upstroke letter 'l' at the fifth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth and sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Ketalar. <u>Route of administration:</u> Ketalar can be administered intravenously or intramuscularly, which would need to be specified on a prescription. Oxtellar XR is only administered orally and does not overlap with the routes of administration for Ketalar.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Ocella (Drospirenone and Ethinyl Estradiol) Tablets <u>Strength:</u> Drospirenone 3 mg and Ethinyl Estradiol 0.03 mg <u>Dosage:</u> One tablet by mouth once daily	<u>Phonetic:</u> Ocella and the root name Oxtellar have three syllables. <u>Dosage and dosage form:</u> Both products can be prescribed as 'Take one tablet.' <u>Frequency of administration:</u> Both products are administered once daily. <u>Route of administration:</u> Both products are administered orally.	<u>Phonetic:</u> The first syllable 'o' and 'ox' sound different when spoken. The second syllable 'cell' and 'tell' sound different when spoken. <u>Strength:</u> Since Ocella is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Ocella.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Opti-Clean II (Contact Lens Product) Solution <u>Dosage:</u> Use as directed	<u>Orthographic:</u> Both names begin with O. The letter 'p' in Opti-Clean II and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in Opti-Clean II and the letter 'e' in Oxtellar XR look similar when scripted. The letter pair 'le' in Opti-Clean II and the letter pair 'll' in Oxtellar XR look similar when scripted. The letter pair 'an' in Opti-Clean II and the letter pair 'ar' in Oxtellar XR look similar when scripted. Both names contain a modifier.	<u>Orthographic:</u> The modifier II and XR look different when scripted. <u>Strength:</u> Since Opti-Clean II is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. <u>Dosage:</u> Opti-Clean II may be prescribed as 'Use as directed' vs. Oxtellar XR will be prescribed as 'Take X tablets.'

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8.	Opti-Clear (Tetrahydrozoline) Solution <u>Strength:</u> 0.05 % <u>Dosage:</u> One to two drops into the affected eye(s) up to four times daily	<u>Orthographic:</u> Both names begin with O. The letter 'p' in Opti-Clear and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in Opti-Clear and the letter 'e' in Oxtellar XR look similar when scripted. The letter pair 'le' in Opti-Clear and the letter pair 'll' in Oxtellar XR look similar when scripted. Both names end with the letter pair 'ar.' <u>Frequency of administration:</u> Opti-Clear can be administered four times daily and Oxtellar XR is administered once daily. The abbreviations QID (four times daily) and QD (daily) look similar when scripted.	<u>Orthographic:</u> If written, the modifier 'XR' would differentiate Oxtellar XR from Opti-Clear. <u>Strength:</u> Since Opti-Clear is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Opti-Clear.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
9.	OptiFlex-G (Glucosamine) Tablets <u>Strength:</u> 750 mg <u>Dosage:</u> 1,500 mg by mouth once daily	<u>Orthographic:</u> Both names begin with O. The letter 'p' in OptiFlex-G and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in OptiFlex-G and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the fifth and sixth position. The letter 'e' in OptiFlex-G and the letter pair 'a' in Oxtellar XR look similar when scripted. Both names contain a modifier. <u>Dosage:</u> The 1,500 mg OptiFlex-G dose can be achieved with one tablet of 300 mg and two tablets of 600 mg of Oxtellar XR. <u>Frequency of administration:</u> Both products are administered once daily. <u>Dosage form:</u> Both products are tablets.	<u>Orthographic:</u> The letter 'f' in Optiflex-G can also provide a down stroke portion in the infix vs. Oxtellar XR does not contain a down stroke letter in the infix. The letter 'x' in OptiFlex-G and the letter 'r' in Oxtellar XR look different when scripted. The modifier G and XR look different when scripted.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
10.	OptiFlex-C (Chondroitin) Capsules <u>Strength:</u> 400 mg <u>Dosage:</u> Two capsules by mouth once daily	<u>Orthographic:</u> Both names begin with O. The letter 'p' in OptiFlex-C and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in OptiFlex-C and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the fifth and sixth position. The letter 'e' in OptiFlex-C and the letter pair 'a' in Oxtellar XR look similar when scripted. Both names contain a modifier. <u>Dosage:</u> Both products can be prescribed as 'Take two.' <u>Frequency of administration:</u> Both products are administered once daily. <u>Route of administration:</u> Both products are administered orally.	<u>Orthographic:</u> The letter 'f' in Optiflex-C can also provide a down stroke portion in the infix vs. Oxtellar XR does not contain a down stroke letter in the infix. The letter 'x' in OptiFlex-C and the letter 'r' in Oxtellar XR look different when scripted. The modifier C and XR look different when scripted. <u>Strength:</u> Since OptiFlex-C is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. Although a 1,200 mg dose of Oxtellar XR can be achieved with three capsules of OptiFlex-C, 1,200 mg of OptiFlex-C is outside the usual dosage range.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
11.	Optivar (Azelastine) Solution Strength: 0.05 % Dosage: One drop in affected eye(s) twice daily	Orthographic: Both names begin with 'O.' The letter 'p' in Optivar and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter 't' at the third position. The letter 'i' in Optivar and the letter 'e' in Oxtellar XR look similar when scripted. Both names end with the letter pair 'ar.'	Orthographic: Optivar does not contain an upstroke letter at the fifth or sixth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth and sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Optivar. Strength: Since Optivar is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Optivar.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
12.	Ovrette (Norgestrel) Tablets <u>Strength:</u> 0.075 mg <u>Dosage:</u> One tablet by mouth once daily	<u>Orthographic:</u> Both names begin with 'O.' The letter 'v' in Ovrette and the letter 'x' in Oxtellar XR look similar when scripted. The letter string 'ett' in Ovrette and the letter string 'ell' in Oxtellar XR look similar when scripted. The letter 'e' at the seventh position in Ovrette and the letter 'a' in Oxtellar XR look similar when scripted. <u>Dosage and dosage form:</u> Both products may be prescribed as 'Take one tablet.' <u>Frequency of administration:</u> Both products are administered once daily.	<u>Orthographic:</u> Ovrette does not contain a cross stroke letter at the third position vs. Oxtellar XR contains a cross stroke letter 't' at the third position. If written, the modifier 'XR' would differentiate Oxtellar XR from Ovrette. <u>Strength:</u> Since Ovrette is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Ovrette.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	Oxacillin Injection Strength: 0.5 g, 1 g, 2 g, and 10 g Dosage: 0.25 g to 2 g intravenously or intramuscularly every four to six hours; 50 mg/kg/day to 100 mg/kg/day intravenously or intramuscularly in equally divided doses every four to six hours in pediatrics; 25 mg/kg/day intravenously or intramuscularly divided every six to twelve hours in neonates	Orthographic: Both names begin with the letter 'Ox.' The letter string 'ill' in Oxacillin and the letter string 'ell' in Oxtellar XR look similar when scripted. The letter pair 'in' in Oxacillin and the letter pair 'ar' in Oxtellar XR look similar when scripted. Dosage: Since the pediatric dosage for Oxacillin has a wide range and is individualized to patient's weight, there is potential overlap in dosage: Oxacillin 300 mg and Oxtellar XR 300 mg Frequency of administration: Oxacillin can be administered every six hours (four times daily) and Oxtellar XR is administered once daily. The abbreviations QID (four times daily) and QD (daily) look similar when scripted.	Orthographic: Oxacillin does not contain a cross stroke letter at the third position vs. Oxtellar XR contains a cross stroke letter 't' at the third position. The letter string 'aci' in Oxacillin and the letter pair 'te' in Oxtellar XR look different when scripted. If written, the modifier 'XR' would differentiate Oxtellar XR from Oxacillin. Route of administration: Oxacillin can be administered intravenously or intramuscularly, which would need to be specified on a prescription. Oxtellar XR is only administered orally and does not overlap with the routes of administration for Oxacillin.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
14.	Antiben (Antyprine and Benzocaine) Solution <u>Strength:</u> Antipyrine 54 mg and Benzocaine 14 mg per mL <u>Dosage:</u> Two to four drops into ear canal (fill ear canal) and repeat every one to two hours as needed	<u>Orthographic:</u> The first letter 'A' and 'O' look similar when scripted. The letter 'n' at the second position in Antiben and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'i' in Antiben and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the fifth position. The letter pair 'en' in Antiben and the letter pair 'ar' in Oxtellar XR look similar when scripted.	<u>Orthographic:</u> Antiben does not contain an upstroke letter at the sixth position vs. Oxtellar XR contains an upstroke letter at the sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Antiben. <u>Strength:</u> Since Antiben is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Antiben. <u>Frequency of administration:</u> Antiben is administered every one to two hours as needed vs. Oxtellar XR is administered once daily.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
15.	(b) (4)		

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

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
16.	Cefaclor Capsules, Extended-release Tablets, Suspension Strength: 250 mg, 500 mg Capsules; 375 mg, 500 mg Extended-release Tablets; 125 mg per 5 mL, 187 mg per 5 mL, 250 mg per 5 mL, 375 mg per 5 mL Suspension Dosage: Immediate release: 250 mg to 500 mg by mouth every 8 hours; 20 mg/kg/day to 40 mg/kg/day by mouth divided every 8 hours; Extended release: One tablet by mouth every 12 hours	Orthographic: The first letter 'C' and 'O' look similar when scripted. Both names contain a cross stroke letter at the third position. The letter 'a' in Cefaclor and the letter 'e' in Oxtellar XR look similar when scripted. The letter string 'lor' in Cefaclor and 'lar' in Oxtellar XR look similar when scripted. Dosage: Since the pediatric dosage of Cefaclor is individualized to a patient's weight, there is potential for overlap in dosage: Cefaclor 300 mg and Oxtellar XR 300 mg. Route of administration: Both products are administered orally.	Orthographic: The letter 'e' in Cefaclor and the letter 'x' in Oxtellar XR look different when scripted. Cefaclor does not contain an upstroke letter at the fifth position vs. Oxtellar XR contains a double upstroke letter pair 'll' at the fifth position and sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Cefaclor.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
17.	Celontin (Methsuximide) Capsules Strength: 150 mg, 300 mg Dosage: 300 mg by mouth once daily for one week, then increase, if necessary, at weekly intervals by 300 mg increments for three weeks up to a maximum of 1.2 g by mouth in three to four divided doses; 10 mg/kg to 15 mg/kg by mouth given in three to four divided doses and increase weekly up to a maximum of 30 mg/kg/day	Orthographic: The first letter 'C' and 'O' look similar when scripted. Both names contain an upstroke letter at the second position. The letter 'o' in Celontin and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the sixth position. The letter pair 'in' in Celontin and the letter pair 'ar' in Oxtellar XR look similar when scripted. Strength: Both products are available in a 150 mg and 300 mg strength. Dosage: Both products may be prescribed 'Take one' Frequency of administration: Both products may be administered once daily Route of administration: Both products are administered orally.	Orthographic: The letter 'e' in Celontin and the letter 'x' in Oxtellar XR look different when scripted. Celontin does not contain an upstroke letter at the fifth position vs. Oxtellar XR contains an upstroke letter at the fifth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Celontin.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
18.	Cytadren (Aminoglutethimide) Tablets Strength: 250 mg Dosage: One tablet by mouth two to three four times daily	Orthographic: The first letter 'C' and 'O' look similar when scripted. The letter 'y' in Cytadren and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'a' in Cytadren and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the fifth position. The letter pair 'en' in Cytadren and 'ar' in Oxtellar XR look similar when scripted. Dosage and dosage form: Both products may be prescribed as 'Take one tablet.' Frequency of administration: Cytadren can be administered four times daily and Oxtellar XR is administered once daily. The abbreviations QID (four times daily) and QD (daily) look similar when scripted.	Orthographic: Cytadren does not contain an upstroke letter at the sixth position vs. Oxtellar XR contains an upstroke letter 'l' at the sixth position. If written, the modifier 'XR' would differentiate Oxtellar XR from Cytadren. Strength: Since Cytadren is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Cytadren.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
19.	Cytotec (Misoprostol) Tablets <u>Strength:</u> 100 mcg, 200 mcg <u>Dosage:</u> One tablet by mouth four times daily	<u>Orthographic:</u> The first letter 'C' and 'O' look similar when scripted. The 'y' in Cytotec and the 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position. The letter 'o' in Cytotec and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain an upstroke letter at the fifth position. The letter 'c' at the last position in Cytotec and the letter 'r' in Oxtellar XR look similar when scripted. <u>Dosage and dosage form:</u> Both products are prescribed as 'Take one tablet.' <u>Frequency of administration:</u> Cytotec can be administered four times daily and Oxtellar XR is administered once daily. The abbreviations QID (four times daily) and QD (daily) look similar when scripted.	<u>Orthographic:</u> Cytotec does not contain an upstroke letter at the sixth position vs. Oxtellar XR contains an upstroke letter 'l' at the sixth position. <u>Strength:</u> Since both products are available in multiple strengths, a strength would need to be specified on a prescription. Although the 300 mg strength of Oxtellar XR can be achieved with three tablets of Cytotec 100 mcg, a 300 mcg dose of Cytotec is outside of the usual dosage range. The strengths of the two products do not overlap.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
20.	Epiflur (Sodium Fluoride) Tablets <u>Strength:</u> 0.25 mg, 0.5 mg, 1 mg <u>Dosage:</u> One tablet by mouth once daily	<u>Orthographic:</u> The first letter 'e' and 'o' look similar when scripted. The letter 'p' in Epiflur and the letter 'x' in Oxtellar XR look similar when scripted. The letter 'i' in Epiflur and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain two upstroke letters in the infix. The letter pair 'ur' in Epiflur and the letter pair 'ar' in Oxtellar XR look similar when scripted. <u>Dosage:</u> Both products can be prescribed as 'Take one tablet.' <u>Frequency of administration:</u> Both products are administered once daily <u>Route of administration:</u> Both products are administered orally.	<u>Orthographic:</u> Epiflur does not contain a cross stroke letter at the third position vs. Oxtellar XR contains the cross stroke letter 't' at the third position. If written, the modifier 'XR' would differentiate Oxtellar XR from Epiflur. <u>Strength:</u> Since both products are available in multiple strengths, a strength would need to be specified on a prescription. The strengths of the two products do not overlap and are not achievable.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
21.	Optulle (Mineral Oil and Petrolatum) Dressing <u>Dosage:</u> Use as directed	<u>Orthographic:</u> Both names begin with 'O.' The letter 'p' in Optulle and the letter 'x' in Oxtellar XR look similar when scripted. Both names contain a cross stroke letter 't' at the third position and two upstroke letters at the fifth and sixth position. The letter 'e' in Optulle and the letter 'a' in Oxtellar XR look similar when scripted.	<u>Strength:</u> Optulle is a topical dressing that does not have a strength. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. <u>Dosage:</u> Oxtellar XR will be prescribed as 'Take X tablets' vs. Optulle will be prescribed as 'Use as directed.'

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
22.	Ostera (Vitamin D, Vitamin K, Berberine, and Reduced Iso-Alpha Acids Complex) Tablets Strength: Vitamin D 500 International Units, Vitamin K 500 mcg, Berberine 90 mg, Reduced Iso-Alpha Acids Complex 370 mg Dosage: One tablet by mouth twice daily	Phonetic: Ostera and the root name Oxtellar have three syllables. The first syllable 'os' and 'ox' sound similar when spoken. The second syllable in both names start with a plosive alveolar consonant. The third syllable in both names start with an alveolar consonant. Dosage and dosage form: Both products can be prescribed as 'Take one tablet.' Route of administration: Both products are administered orally.	Phonetic: The second syllable 'ter' and 'tel' sound different when spoken. 'The third syllable 'a' and 'ar' sound different when spoken. Strength: Since Ostera is available in one strength, the strength may be omitted from a prescription. Since Oxtellar XR is available in multiple strengths, a strength would need to be specified on a prescription. The strengths of Oxtellar XR do not overlap and are not achievable with the strength of Ostera.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
23.	Vetalar (Ketamine) Injection <u>Strength:</u> 100 mg per mL <u>Dosage:</u> 0.5 mg/kg to 4.5 mg/kg intravenously; 0.5 mg/kg/min intravenously with diazepam induction; 0.1 mg/min to 0.5 mg/minute intravenously with diazepam maintenance; 3.25 mg/kg to 13 mg/kg intramuscularly	<u>Orthographic:</u> Both names contain a cross stroke letter 't' at the third position. The letter 'a' at the fourth position of Vetalar and the letter 'e' in Oxtellar XR look similar when scripted. Both names contain the letter string 'lar' in the suffix. <u>Dosage:</u> Since the dosage for Vetalar has a wide range and is individualized to patient's weight, there is potential for overlap in dosage: Vetalar 300 mg vs. Oxtellar XR 300 mg	<u>Orthographic:</u> The first letter 'V' and 'O' look different when scripted. The letter 'e' in Vetalar and the letter 'x' in Oxtellar XR look different when scripted. If written, the modifier 'XR' would differentiate Oxtellar XR from Vetalar. <u>Route of administration:</u> Vetalar can be administered intravenously or intramuscularly, which would need to be specified on a prescription. Oxtellar XR is only administered orally and does not overlap with the routes of administration for Vetalar.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.			
No.	**Proposed name:** Oxtellar XR **Dosage Form:** Extended-release Tablets **Strength:** 150 mg, 300 mg, 600 mg **Dosage:** ***Adults:*** 600 mg once daily and increase up to 600 mg per day at weekly intervals. The recommended daily dose is 1,200 mg to 2,400 mg once daily. ***Children:*** 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily. ***Renal Impairment:*** One-half the usual starting dose and increase slowly to achieve the desired clinical response.	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
24.	(b) (4)		

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/s/

JULIE V NESHIEWAT
10/10/2012

IRENE Z CHAN
10/11/2012

CAROL A HOLQUIST
10/11/2012

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

Proprietary Name Review

Date:	May 3, 2012
Reviewer:	Loretta Holmes, BSN, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director	Carol A. Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	(b) (4) (Oxcarbazepine) Extended-release Tablets 150 mg, 300 mg, and 600 mg
Application Type/Number:	NDA 202810
Applicant:	Supernus Pharmaceuticals
OSE RCM #:	2012-373

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, (b) (4), from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The Applicant initially submitted the name (b) (4) for this product when it was in the IND phase of review. DMEPA found that name acceptable in OSE Review 2009-1012. However, the Applicant decided to submit a different name, (b) (4), under the NDA because the name (b) (4) was thought to be too similar to the newly approved product (b) (4).

This NDA is a 505(b)(2) application. The Reference Listed Drugs (RLD) are Trileptal oral tablets and Trileptal oral suspension.

1.2 PRODUCT INFORMATION

The following product information is provided in the February 8, 2012 proprietary name submission.

- **Active Ingredient:** Oxcarbazepine
- **Indication of Use:** Adjunctive therapy in the treatment of partial seizures in adults and in children aged (b) (4) to 17 years old
- **Route of administration:** Oral
- **Dosage form:** Extended-release Tablets
- **Strength:** 150 mg, 300 mg, and 600 mg
- **Dose and Frequency of Administration:**

  Adults: Initiate with a dose of 600 mg/day; given once daily. The dose may be increased by a maximum of 600 mg/day at approximately weekly intervals. The recommended daily dose is between 1200 mg to 2400 mg per day.

  Children: 8 mg/kg to 10 mg/kg once daily, generally not to exceed 600 mg once daily.

  Patients with Renal Impairment: In patients with impaired renal function (creatinine clearance less than 30 mL/min), therapy should be initiated at one-half the usual starting dose (300 mg per day) and increased slowly to achieve the desired clinical response.
- **How Supplied:** 100 count bottles and 5 count physicians sample blister cards
- **Storage:** 25ºC (77ºF); excursions permitted between 15ºC and 30ºC (59ºF to 86ºF)
- **Derivation of root name "(b) (4)":** According to the Applicant, "the proposed name (b) (4) was not derived from any one particular concept."

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/s/

LORETTA HOLMES
05/03/2012

CAROL A HOLQUIST on behalf of IRENE Z CHAN
05/03/2012
Signing on behalf of IRENE CHAN

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
05/04/2012
Signing on behalf of Kellie Taylor

CAROL A HOLQUIST
05/04/2012