CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202211s000

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--Final

Date:	December 11, 2012
Reviewer:	James Schlick, RPh, MBA Division of Medication Error Prevention and Analysis
Team Leader	Todd Bridges, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Oxytrol for Women (Oxybutynin) Transdermal System 3.9 mg/day
Application Type/Number:	NDA 202211
Applicant:	MSD Consumer Care, Inc
OSE RCM #:	2012-2012

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CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Oxytrol for Women is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Oxytrol for Women, acceptable in OSE Review # 2012-785 dated June 21, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review # 2012-785. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. A search of the databases yielded no new names thought to look or sound similar to Oxytrol for Women and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of December 10, 2012.

The Division of Nonprescription Clinical Evaluation (DNCE) reviewed the proposed name on May 31, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Oxytrol for Women, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Oxytrol for Women, for this product at this time.

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

If you have questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

4 REFERENCES

1. **OSE Review 2012-785. Oxytrol for Women Proprietary Name Review. June 21, 2012.**

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

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

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

   USAN Stems List contains all the recognized USAN stems.

4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***

   Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

/s/

JAMES H SCHLICK
12/11/2012

TODD D BRIDGES
12/11/2012

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:	June 21, 2012
Reviewer(s):	James Schlick, RPh, MBA Division of Medication Error Prevention and Analysis
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Drug Name(s) and Strength(s):	Oxytrol for Women (Oxybutynin) Transdermal System 3.9 mg/day
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Applicant:	MSD Consumer Care, Inc.
OSE RCM #:	2012-785

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Oxytrol for Women, 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 proposed proprietary name, Oxytrol for Women, was found acceptable by DMEPA in OSE Review 2010-1491, dated December 17, 2010, under IND 074288. The applicant submitted a proprietary name request on March 26, 2012, for NDA 202211, which is the topic of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 26, 2012 proprietary name submission.

- Active Ingredient: Oxybutynin
- Indication of Use: Nonprescription treatment of overactive bladder in women
- Route of Administration: Transdermal
- Dosage Form: Matrix-type transdermal patch
- Strength: 3.9 mg/day
- Dose and Frequency: Apply one patch and wear it for four consecutive days. After 4 days, remove the used patch and apply a new one.
- How Supplied: One patch in an individual sealed pouch
- Storage: Store between 20°C to 25°C (68°F to 77°F).
- Container and Closure Systems: Four individually sealed pouches per carton

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Division of Nonprescription Clinical Evaluation (DNCE), based on their May 31, 2012, review submitted in DARRTS, determined the proposed name is acceptable from a promotional perspective. DMEPA concurred with the findings of DNCE's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On April 23, 2012 the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed name, Oxytrol for Women, contains two components: 1) the proposed root name, Oxytrol, and 2) a modifier, for Women. In the proprietary name submission, the sponsor provided the following rationale for the components of the name:

> *Watson Pharmaceuticals, Inc. currently markets Oxytrol (oxybutynin transdermal system, 3.9 mg/day) as an Rx product under NDA 21-351. Merck Consumer Care Products, Inc. (MCC) has an agreement with Watson to switch the marketing status of Oxytrol to over-the-counter. SPHCP's planned OTC switch is for the target population of women, aged 18 and over. The use of Oxytrol by males will remain a prescription indication.*
>
> *The name "Oxytrol for Women" utilizes the current Rx proprietary name "Oxytrol", modified with "for Women" to communicate that the OTC product is for use by women and to differentiate the OTC product from the Rx product. This communication is enhanced by the feminine graphics and color of the package. In the case where an OTC product and Rx product will be marketed simultaneously, the Agency has previously found it acceptable to differentiate the Rx product from the OTC product by the use of a modifier.*

2.2.3 Medication Error Data Selection of Cases

Since Oxytrol is currently marketed, DMEPA searched AERS database for medication errors involving Oxytrol which would be relevant for this review.

The April 23, 2012 search of the Adverse Event Reporting System (AERS) database used the following search terms: active ingredient "Oxybutynin", trade name "Oxytrol", and verbatim terms "Oxybut%" and "Oxyt%". The reaction terms used were the MedDRA High Level Group terms (HLGT) "Medication Errors" and "Product Quality Issues". The last AERS search conducted for Oxytrol was November 1, 2010 in OSE review 2010-1491.

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the types of errors and contributing factors to the error when provided by the reporter.

This search strategy yielded 19 cases. All of these cases were excluded for the following reasons: foreign cases and cases not related to the Oxytrol transdermal dosage form.

2.2.4 FDA Name Simulation Studies

Thirty-three practitioners participated in DMEPA's prescription studies. Four responses were identified as similar to the currently marketed product, Oxitrol. However, the responses included the root "Oxitrol" with the modifier "for Women". Name confusion with Oxitrol is assessed in Appendix E.

Twenty of the 33 participants spelled the name correctly. Five participants dropped the modifier "for Women" in the inpatient and outpatient prescription simulations. Participants spelled the root name Oxytrol incorrectly in eight of the 12 voice prescription simulations. With those responses the letter string 'Oxy' was mistaken for the letter string 'Axe', 'Ocs', and 'Oxa'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Failure Mode and Effects Analysis of Similar Names and Modifier "for Women"

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Oxytrol for Women. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Oxytrol for Women, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation and names from OSE Review# 2010-1491.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and FDA Name Simulation Studies)

Look Similar		**Look Similar**		**Look and Sound Similar**	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Axiron	FDA	Oxycel	FDA	Amytal	FDA
Opti-Heat	FDA	Oxycet	FDA	Maxitrol	FDA
OptiNate	FDA	Oxy-Clean	FDA	Oxgall	FDA
Ox-Bile	FDA	OxyFast	FDA	Oxytrol	FDA
Oxilan	FDA	OxyIR	FDA	Oxybutynin	FDA
Oxipor	FDA	Oxy-Otic	FDA	Osmitrol	FDA
Oxybate	FDA	Oxytrex***	FDA	Ocu-Trol	FDA
Detrol	FDA	Oxychinol	FDA	Uroxatral	FDA
Optilets-M	FDA	Oxycontin	FDA	Oxitrol	FDA
Oryzanol	FDA	Oxyfrin	FDA		

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Look Similar		Look Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Q-naftate	FDA	Oxylone	FDA		
Oxiplen	FDA	Oxytocin	FDA		
Oxistat	FDA	Oyst-Cal-D	FDA		
Minoxidil for Women	FDA	Rogaine for Women	FDA		
Oxygel	FDA	Onxol	FDA		

Our analysis of the 39 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 37 names will not pose a risk for sound alike or look alike confusion as described in Appendix D and E. The remaining two names, Oxytrol and Oxitrol, are discussed below.

Confusion between Oxytrol and Oxytrol for Women

Our evaluation determined that the name, Oxytrol, could be confused with the proposed name, Oxytrol for Women, if the modifier is omitted. However, this confusion would result in patients receiving a product identical to the intended product. Since the patient would receive a product identical to the intended product if name confusion occurred, this would not be considered a medication error and is not cause for name objection.

Confusion between Oxitrol and Oxytrol for Women

The name, Oxitrol, could be confused with the proposed name Oxytrol for Women. However, introducing the proposed product into the marketplace under a root name other than Oxytrol also has risks. Specifically, this may result in concomitant therapy with the currently marketed Oxytrol prescription product if practitioners are not aware that the proposed product contains oxybutynin. We have seen such duplicate therapy post-marketing with other products that have different proprietary names but the same active ingredient. For example, duplicate therapy has occurred when a patient was accidentally discharged from the hospital on both Jantoven (warfarin) and Coumadin (warfarin).

We also believe confusion between the proposed product and Oxitrol will be minimized by the following factors: the modifier "for Women" will provide orthographic and phonetic differences when it is spoken or written; there are no reports of confusion between the currently marketed prescription product Oxytrol and Oxitrol; availability of Oxitrol is limited to online specialty vitamin retailers and to licensed health care providers to sell to patients through their practices; and differentiating product characteristics such as frequency of administration (once daily versus every 3 to 4 days) and dosage form (capsule for oral administration versus a transdermal patch).

Therefore, we conclude using the root name Oxytrol for the proposed product has less risk for errors than marketing it under an alternate root name.

Modifier “for Women”

With respect to the modifier “for Women”, no data was provided to support that this modifier would not inadvertently introduce a source of error. However, this modifier is used for other marketed nonprescription products to represent the intended population of use (e.g., Rogaine and Minoxidil for Women and numerous multivitamin or laxative products). There appears to be no established association with the modifiers “for Women” and a particular active ingredient, nor any errors associated with the modifier. The Applicant’s intended meaning of the modifier follows this trend because the proposed product is intended for use in women 18 years of age and over. Although this applicant has not provided data to support the use of the proposed modifier, DMEPA believes that the use of these modifiers in the nomenclature of similar marketed products adequately supports their use for the proposed product. Thus, in consideration of the total data available, DMEPA does not believe the modifiers “for Women” represent a safety concern.

2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Nonprescription Clinical Evaluation via email on June 8, 2012. At the time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Nonprescription Clinical Evaluation on June 15, 2012, they stated no additional concerns with the proposed proprietary name, Oxytrol for Women.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Oxytrol for Women, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your March 26, 2012 submission are altered, the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

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 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.

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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.

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]

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 2 below for details).

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

Table 2. 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 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, Oxytrol for Women	Scripted May Appear as	Spoken May Be Interpreted as
'O'	'Q', 'D', 'A', 'U', '0'	'Oh', Any vowel
'o'	'a', 'c', 'e', 'u'	'oh', Any vowel
'x'	'r', 'a', 'd', 'f', 'k', 'n', 'p', 't', 'v', 'y'	'ks', 'kz', 's', 'z', 'c'
'y'	'p', 'f', 'u', 'v', 'x', 'z'	'e', 'i', 'u'
't'	'b', 'l', 'f', 'r', 'x', 'A'	'd'
'r'	's', 'n', 'e', 'v'	
'l'	'b', 'e', 'A', 's', 'P', 'i'	
'f'	'f'	
'W'	'IV', 'eu'	
'w'	'eu'	
'm'	'rn', 'nn', 'n', v', 'w', 'wi', 'vi', 'onc', 'z'	'n'
'e'	'a', 'i', 'l', 'o', 'u', 'p'	Any vowel
'n'	'm', 'u', 'x', 'r', 'h', 's'	'm', 'dn', 'gn', 'kn', 'nn', 'pn

Appendix C: Prescription Simulation Samples and Results

Figure 1. Oxytrol for Women Study (Conducted on 04/20/2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Oxytrol for Women Apply as directed. Change every 4 days.	Oxytrol for Women Sig: Apply as directed. Change every 4 days. Disp: #7
Outpatient Prescription: Oxytrol for Women # 7 patches Sig: Apply as directed. Change every 4 days.	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study
33 People Responded

Study Name: **Oxytrol for Women** **As of 05/08/2012**

Total	12	12	9	33
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
AXETOL FOR WOMEN	0	1	0	1
OCSATROL FOR WOMEN	0	1	0	1
OXATROL FOR WOMEN	0	2	0	2
OXITROL FOR WOMEN	0	4	0	4
OXYTROL	2	0	3	5
OXYTROL FOR WOMEN	10	4	6	20

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

Proprietary Name	Active Ingredient	Similarity to Oxytrol for Women	Failure preventions
Axiron	Testosterone	Looks alike	The pair has sufficient orthographic differences.
Oxilan	Ioxilan	Looks alike	The pair has sufficient orthographic differences.
Oxipor	Coal Tar	Looks alike	The pair has sufficient orthographic differences.
Opti-Heat		Looks alike	Name identified in Red Book (Deactivated 1/15/1996) and USPTO database ("Dead" 11/3/2007). Unable to find product characteristics in other commonly used drug databases. USPTO states the name is for an electric disinfection unit for contact lenses.
Oxychinol	Oxyquinoline	Looks alike	Name identified in Red Book (Deactivated 11/22/1995). Unable to find product characteristics in other commonly used drug databases.
Oxgall	Betaxolol	Looks and sounds alike	Name identified in Red Book (Deactivated 10/02/2000). Unable to find product characteristics in other commonly used drug databases.
(b) (4)			Proposed name found unacceptable by DMEPA (RCM# 2006-578 and 2006-584; dated 07/13/2007). Product was approved on 1/27/2009 with the name Gelnique.

*** 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.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
OptiNate Pre-Natal Multivitamin/ Mineral Capsules <u>Usual Dose</u> 1 capsule orally daily	<u>Orthographic</u> The name OptiNate has upstroke and downstroke letters in similar positions to Oxytrol. Both names begin with the letter 'O'. <u>Dose</u> Both products can be written as one capsule or one patch. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> The name OptiNate has the down stroke letter 'p' in the second position where Oxytrol does not. OptiNate has a cross stroke letter 't' near the end of the name where Oxytrol does not. OptiNate has the letter 'e' at the end of the name where Oxytrol ends with the upstroke letter 'l'. The modifier adds orthographic difference when included. <u>Frequency of Administration</u> Daily vs. every four days
Ox-Bile (Lyopholized Bovine Bile) Capsules 125 mg and 500 mg <u>Usual Dose</u> 1 to 3 capsules orally three times daily with meals	<u>Orthographic</u> The name Ox-Bile can have up stroke and downstroke letters in similar positions to Oxytrol, especially if Ox-Bile is scripted without the dash and the letter 'b' is in lower case. Both names begin with the letter 'O'. <u>Dose</u> Both products can be written as one capsule or one patch.	<u>Orthographic</u> The name Oxytrol has the downstroke letter 'y' in the second position where Ox-Bile does not. The modifier adds orthographic difference when included. <u>Strength</u> Ox-Bile has multiple strengths that would need to be indicated on a prescription while Oxytrol for Women has just one strength. There is no overlap or numerical similarity between strengths. <u>Frequency of Administration</u> Three times daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxybate (Sodium Oxybate) Oral Solution 375 mg/mL <u>Usual Dose</u> 2.25 grams to 4.5 grams orally (6 mL to 12 mL) twice daily. One dose at bedtime and one dose 3 to 4 hours later.	<u>Orthographic</u> Both names begin with the letter string 'Oxy'. The letter string 'ba' looks similar to the letter string 'tro'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> Oxybate has a cross stroke letter 't' and the letter 'e' at the end of the name where Oxytrol does not. The modifier adds orthographic difference when included. <u>Dose</u> There is no overlap or numerical similarity between doses. <u>Frequency of Administration</u> Twice daily vs. every 4 days
Detrol (Tolterodine) Tablets 1 mg and 2 mg <u>Usual Dose</u> 1 mg to 2 mg orally twice daily	<u>Orthographic</u> The letter 'D' can look similar to the letter 'O'. Both names end with the letter string 'trol'. <u>Setting of Use</u> Both products are used to treat overactive bladder.	<u>Orthographic</u> The letter string 'xy' in Oxytrol does not look similar to the letter 'e' in Detrol. The modifier adds orthographic difference when included. <u>Strength</u> Detrol has multiple strengths that would need to be indicated on a prescription while Oxytrol for Women has just one strength. There is no overlap or numerical similarity between strengths. <u>Frequency of Administration</u> Twice daily vs. every 4 days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Optilets-M (Multivitamin/Mineral) Filmtab Tablets <u>Usual Dose</u> 1 to 2 tablets orally once daily	<u>Orthographic</u> The name Optilets has upstroke and downstroke letters in similar positions to Oxytrol. Both names begin with the letter 'O'. <u>Dose</u> Both products can be written as one tablet or one patch. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> The name Oxytrol has the letter 'x' in the second position before the downstroke and cross stroke combination 'yt'. Optilets-M does not have the letter 'x' before its downstroke and cross stroke combination 'pt'. Optilets-M has three upstroke letters where Oxytrol has two. Optilets-M has a cross stroke letter 't' near the end of the name where Oxytrol does not. <u>Frequency of Administration</u> Daily vs. every four days
Oryzanol (Gamma Oryzanol) Tablets 60 mg <u>Usual Dose</u> 1 to 4 tablets orally once daily	<u>Orthographic</u> The letter string 'Ory' can look similar to the letter string 'Oxy' when scripted. The letter string 'nol' can look similar to the letter string 'rol' when scripted. <u>Dose</u> Both products can be written as one tablet or one patch. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> Oxytrol has a cross stroke letter 't' in the middle of the name where Oryzanol does not. The modifier adds orthographic difference when included. <u>Frequency of Administration</u> Daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Q-Naftate (Tolnaftate) Cream, Powder, Topical Solution 1% <u>Usual Dose</u> Apply to affected area topically twice daily	<u>Orthographic</u> The letter 'Q' can look similar to the letter 'O' when scripted. The name Q-naftate has upstroke and downstroke letters in similar positions to Oxytrol. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Directions for Use</u> Both products may be ordered with abbreviated directions for use such as "apply as directed".	<u>Orthographic</u> Q-Naftate has three upstroke letters where Oxytrol has only two upstroke letters. Q-Naftate has a cross stroke letter 't' at the end of the name where Oxytrol does not. The modifier adds orthographic difference when included.
Oxiplen (Multivitamin/Mineral) Capsule <u>Usual Dose</u> 1 to 2 capsules orally once daily	<u>Orthographic</u> Both names begin with the letter string 'Ox'. Both names have a downstroke and an upstroke letter together in a similar position; 'pl' and 'yt'. <u>Dose</u> Both products can be written as one capsule or one patch. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> Oxytrol has an upstroke letter 'l' at the end of the name where Oxiplen does not. The modifier adds orthographic difference when included. <u>Frequency of Administration</u> Daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxistat (Oxiconazole) Cream and Lotion 1% Usual Dose Apply to affected area topically once to twice daily	Orthographic Both names begin with the letter string 'Ox'. Both names have the letter 't' in a similar position. Strength Both products are single strength; thus, the strength may be omitted. Directions for Use Both products may be ordered with abbreviated directions for use such as "apply as directed".	Orthographic Oxytrol has a down stroke letter 'y' in the third position where Oxistat does not have a downstroke letter. Oxistat has a cross stroke letter 't' at the end of the name where Oxytrol does not. The modifier adds orthographic difference when included.
Oxycel Oxidized Cellulose Pads: 3" x 3" Pledgets: 2" x 1" x 1" Strips: 18" x 2"; 5" x ½"; 36" x ½" Usual Dose Lay on bleeding site or held firmly against the tissues until hemostasis is obtained.	Orthographic Both names begin with the letter string 'Oxy'. The letter string 'cel' can look similar to the letter string 'rol' when scripted. Directions for Use Both products may be ordered with abbreviated directions for use such as "as directed".	Orthographic Oxytrol has the cross stroke letter 't' in the middle of the name where Oxycel does not have a cross stroke letter. The modifier adds orthographic difference when included. Setting of Use Oxycel is used in surgical procedures in the operating room.
Oxycet (Oxycodone/Acetaminophen) Tablet 5 mg/325 mg Usual Dose 1 tablet orally every 6 hours as needed for pain	Orthographic Both names begin with the letter string 'Oxy'. The letter string 'ce' can look similar to the letter string 'ro' when scripted. Strength Both products are single strength; thus, the strength may be omitted. Dose Both products can be written as one tablet or one patch.	Orthographic Oxytrol has the cross stroke letter 't' in the middle of the name where Oxycet does not. Oxycet has a cross stroke letter 't' at the end of the name where Oxytrol does not. The modifier adds orthographic difference when included. Frequency of Administration Every 6 hours as needed for pain vs. every 4 days.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxy-Clean (Salicylic Acid) Cleansing Pad and Liquid 0.5% <u>Usual Dose</u> Apply to face once daily	<u>Orthographic</u> Both names begin with the letter string 'Oxy'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Directions for Use</u> Both products may be ordered with abbreviated directions for use such as "as directed".	<u>Orthographic</u> Oxytrol has the cross stroke letter 't' in the middle of the name where Oxy-Clean does not. Oxytrol has an upstroke letter 'l' at the end of the name where Oxy-Clean does not. The modifier adds orthographic difference when included.
OxyFast (Oxycodone) Oral Solution 20 mg/mL <u>Usual Dose</u> 0.5 mL to 3 mL orally every 4 to 6 hours as needed	<u>Orthographic</u> Both names begin with the letter string 'Oxy'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one mL or one patch. <u>Frequency of Administration</u> If the prescription for OxyFast is written for "every 4 hours", this may be mistaken for "every 4 days".	<u>Orthographic</u> Oxytrol has the cross stroke letter 't' in the middle of the name where OxyFast does not. OxyFast has the cross stroke letter 't' at the end of the name where Oxytrol does not.. The modifier adds orthographic difference when included.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
OxyIR (Oxycodone) Capsule 5 mg <u>Usual Dose</u> 1 to 2 capsules orally every 4 to 6 hours as needed.	<u>Orthographic</u> Both names begin with the letter string 'Oxy'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one capsule or one patch. <u>Frequency of Administration</u> If the prescription for OxyIR is written for "every 4 hours", this may be mistaken for "every 4 days".	<u>Orthographic</u> OxyIR has five letters in the name where Oxytrol has seven letters; thus, Oxytrol appears longer when scripted. Oxytrol has a cross stroke letter 't' in the middle of the name where OxyIR does not. The modifier adds orthographic difference when included.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxy-Otic (Carbamide Peroxide) Otic Solution 6.5% <u>Usual Dose</u> 3 to 10 drops in the ear twice daily for up to 4 days.	<u>Orthographic</u> Both names begin with the letter string 'Oxy'. Both names have the letter 't' in a similar position. <u>Strength</u> Both products are single strength; thus, the strength may be omitted.	<u>Orthographic</u> Oxytrol has an upstroke letter 'l' at the end of the name where Oxy-Otic does not. Oxy-Otic has the letter 'o' between the downstroke letter 'y' and the cross stroke letter 't'. The modifier adds orthographic difference when included. <u>Dose</u> There is no overlap or numerical similarity between doses. <u>Frequency of Administration</u> Twice daily vs. every 4 days
Oxytrex[***] (Oxycodone/Naltrexone) Capsule (b) (4)	<u>Orthographic</u> Both names begin with the letter string 'Oxytr'.	<u>Orthographic</u> Oxytrol ends with the upstroke letter 'l' where Oxytrex does not. The modifier adds orthographic difference when included. Strength (b) (4) Oxytrol for Women has just one strength. (b) (4) <u>Frequency of Administration</u> (b) (4) vs. every 4 days

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

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxycontin (Oxycodone) Tablet, Extended Release 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg <u>Usual Dose</u> 10 mg to 80 mg orally twice daily	<u>Orthographic</u> Both names begin with the letter string 'Oxy'.	<u>Orthographic</u> Oxytrol has seven letters in the name where Oxycontin has nine letters; thus, Oxytrol looks shorter when scripted. Oxytrol has the cross stroke letter 't' in the middle of the name where Oxycontin has the letter 't' near the end of the name. The modifier adds orthographic difference when included. <u>Strength</u> Oxycontin has multiple strengths that would need to be indicated on a prescription while Oxytrol for Women has just one strength. There is no overlap or numerical similarity between strengths. <u>Frequency of Administration</u> Twice daily vs. every four days
Oxyfrin (Oxymetazoline) Nasal Solution 0.05% <u>Usual Dose</u> 1 to 2 drops in each nostril twice daily	<u>Orthographic</u> The letter string 'Oxyfr' can look similar to the letter string 'Oxytr' when scripted. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one drop or one patch.	<u>Orthographic</u> Oxytrol has the upstroke letter 'l' at the end of the name where Oxyfrin does not. The modifier adds orthographic difference when included. <u>Frequency of Administration</u> Twice daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxylone (Fluorometholone) Topical Cream 0.025% Usual Dose Apply to affected area twice daily	Orthographic Both names begin with the letter string 'Oxy'. Strength Both products are single strength; thus, the strength may be omitted. Directions for Use Both products may be ordered with abbreviated directions for use such as "use as directed".	Orthographic Oxytrol has the cross stroke letter 't' in the third position where Oxylone does not. Oxytrol has the upstroke letter 'l' at the end of the name where Oxylone does not. The modifier adds orthographic difference when included.
Oxytocin Injection 10 USP/mL Usual Dose 5 ml to 50 mL per hour intravenously via continuous infusion 10 units via intramuscular injection once	Orthographic Both names begin with the letter string 'Oxyt'. Dose If the rate of the continuous infusion is set at 39 ml/hr, this could be mistaken as 3.9 mg/day. Strength Both products are single strength; thus, the strength may be omitted.	Orthographic Oxytrol ends with the upstroke letter 'l' where Oxytocin does not end with an upstroke letter. The modifier adds orthographic difference when included. Frequency of Administration Once or via continuous infusion vs. every 4 days
Oyst-Cal-D (Calcium Carbonate/ Vitamin D) Tablet 250 mg/125 International Units Usual Dose 1 to 2 tablets orally once daily	Orthographic The name Oyst-Cal-D has upstroke and downstroke letters in similar positions to Oxytrol. Both names begin with the letter 'O'. Strength Both products are single strength; thus, the strength may be omitted. Dose Both products can be written as one tablet or one patch.	Orthographic Oxytrol has the letter 'x' in the second position before the downstroke and cross stroke combination 'yt'. Oyst-Cal-D does not have the letter 'x' before the downstroke and cross stroke combination 'yst'. Oyst-Cal-D has the letter 's' between the downstroke letter 'y' and the cross stroke letter 't'. The modifier adds orthographic difference when included. Frequency of Administration Daily vs. every 4 days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Amytal (Amobarbital) Powder for Injection 500 mg per vial <u>Usual Dose</u> Hypnotic: 65 mg to 200 mg via intramuscular injection or intravenous injection once before surgery. Sedative: 30 mg to 50 mg via intramuscular or intravenous injection 2 to 3 times per day.	<u>Orthographic</u> The letter string 'Amy' can look similar to the letter string 'Oxy' when scripted. The letter string 'tal' can look similar to the letter string 'trol' when scripted. <u>Phonetic</u> The letter string 'tal' is phonetically similar to the letter string 'trol'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> A dose of 39 mg for Amytal could be mistaken for 3.9 mg/day.	<u>Orthographic</u> The modifier adds orthographic difference when included. <u>Phonetic</u> The letter string 'Am' is not phonetically similar to the letter string 'Ox'. <u>Frequency of Administration</u> Twice to three times daily or once before surgery vs. every 4 days.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Maxitrol (Dexamethasone/ Neomycin Sulfate/ Polymixin B Sulfate) Ophthalmic Ointment and Ophthalmic Suspension Suspension: 0.1%; 3.5 mg/mL; 10,000 units/mL Ointment: 0.1%; 3.5 mg/gm; 10,000 units/gm <u>Usual Dose</u> Suspension/Drops: 1 to 2 drops in the eye four times daily Ointment: Apply to the affected eye four times daily	<u>Orthographic</u> Both names have the letter 'x' in a similar position. Both names end in the letter string 'trol'. <u>Phonetic</u> The name Maxitrol is phonetically similar to the name Oxytrol. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one drop or one patch. <u>Directions for Use</u> Both products may be ordered with abbreviated directions for use such as "use as directed".	<u>Orthographic</u> The letter string 'Max' does not look similar to the letter string 'Oxy'. The modifier adds orthographic difference when included. <u>Phonetic</u> The modifier adds phonetic difference when included. <u>Multiple Dosage Forms</u> Maxitrol has multiple dosage forms that would need to be indicated on the prescription. Oxytrol has only one dosage form. Thus, the route of administration may be omitted.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Oxybutynin Tablet, Extended Release Tablet, Solution, Syrup, Topical Gel Tablet: 5mg Extended Release Tablet: 5 mg, 10 mg, 15 mg Solution and Syrup: 1 mg/mL Gel: 3% and 10% <u>Usual Dose</u> Tablet, Syrup, Solution: 5 mg orally twice daily to four times daily Extended Release Tablet: 5 mg to 30 mg orally once daily Topical Gel 10%: Apply to skin once daily Topical Gel 3% Apply 3 pumps to skin once daily	<u>Orthographic</u> The letter string 'Oxyb' can look similar to the letter string Oxyt' when scripted. <u>Phonetic</u> Both names begin with the letter 'Oxy'.	<u>Orthographic</u> Oxybutynin has ten letters in the name where Oxytrol has seven letters; thus, Oxytrol appears shorter than Oxybutynin when scripted. Oxytrol has an upstroke letter 'l' the end of the name where Oxybutynin does not have an upstroke letter. The modifier adds orthographic difference when included. <u>Phonetic</u> The letter string 'butynin' is not phonetically similar to the letter string 'trol'. <u>Frequency of Administration</u> There is no overlap or numerical similarity between products. <u>Multiple Dosage Forms</u> Oxybutynin has multiple dosage forms where Oxytrol for Women has only one dosage from. <u>Routes of Administration</u> Oxybutynin has multiple routes of administration that would need to be indicated on the prescription. Oxytrol for Women has only one route of administration. Thus, the route of administration may be omitted. <u>Strength</u> There is no overlap or numerical similarity between strengths. <u>Dose</u> There is no overlap or numerical similarity between doses.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Osmitrol (Mannitol) Solution for Injection Pre-mixed bags 5%, 10%, 15%, 20% <u>Usual Dose</u> 25 to 75 ml per hour via continuous infusion Or 0.1 to 0.2 gram per kg/hr	<u>Orthographic</u> Both names begin with the letter 'O'. Both names end with the letter string 'trol'. <u>Phonetic</u> The name Osmitrol is phonetically similar to the name Oxytrol. <u>Dose</u> If the rate of the continuous infusion is set at 39 ml/hr, this could be mistaken as 3.9 mg/day.	<u>Orthographic</u> Oxytrol has the downstroke letter 'y' in the name where Osmitrol does not have a downstroke letter in the name. The modifier adds orthographic difference when included. <u>Phonetic</u> The modifier adds phonetic difference when included. <u>Strength</u> Osmitrol has multiple strengths that would need to be indicated on the prescription. <u>Frequency of Administration</u> Via continuous infusion vs. every 4 days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Ocu-Trol (Dexamethasone/ Neomycin Sulfate/ Polymixin B Sulfate) Ophthalmic Ointment and Ophthalmic Suspension Suspension: 0.1%; 3.5 mg/mL; 10,000 units/mL Ointment: 0.1%; 3.5 mg/gm; 10,000 units/gm <u>Usual Dose</u> Suspension/Drops: 1 to 2 drops in the eye four times daily Ointment: Apply to the affected eye four times daily	<u>Orthographic</u> Both names begin with the letter 'O'. Both names end with the letter string 'trol'. <u>Phonetic</u> The letter string 'Oc' is phonetically similar to the letter string 'Ox'. Both names end in the letter string 'trol'. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one drop or one patch. <u>Directions for Use</u> Both products may be ordered with abbreviated directions for use such as "use as directed".	<u>Orthographic</u> Oxytrol has a downstroke letter 'y' in the name where Ocu-Trol does not have a downstroke letter in the name. The modifier adds orthographic difference when included. <u>Phonetic</u> The modifier adds phonetic difference when included. <u>Multiple Dosage Forms</u> Ocu-Trol has multiple dosage forms that would need to be indicated on the prescription. Oxytrol has only one dosage form. Thus, the route of administration may be omitted.

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Uroxatral (Alfuzosin) Extended Release Tablet 10 mg <u>Usual Dose</u> 10 mg orally once daily	<u>Orthographic</u> The first letter 'U' can look similar to the first letter 'O' when scripted. Both names have the letter 'x' in similar positions. The letter string 'tral' can look similar to the letter string 'trol'. <u>Phonetic</u> The letter string 'oxatral' in the name Uroxatral is phonetically similar to the name Oxytrol. <u>Strength</u> Both products are single strength; thus, the strength may be omitted. <u>Dose</u> Both products can be written as one tablet or one patch. <u>Settings of Use</u> Both drugs can be used to treat symptoms of urinary frequency.	<u>Orthographic</u> Oxytrol has the downstroke letter 'y' in the name where Uroxatral does not. The modifier adds orthographic difference when included. <u>Phonetic</u> Uroxatral has four syllables where Oxytrol has three syllables. The modifier adds phonetic difference when included. <u>Frequency of Administration</u> Daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Minoxidil for Women (Minoxidil) Topical Solution 2% Usual Dose Apply one mL twice daily topically to the area of desired hair growth.	Orthographic Both names have the modifier "for Women" in the name. Route of Administration Topical Strength Both products have only one strength which may be omitted from the prescription. Dose The dose for both products may be written as UAD (Use as directed).	Orthographic The root names provide sufficient orthographic differences. Frequency of Administration Twice daily vs. every four days
Rogaine for Women (Minoxidil) Topical Solution 2% Usual Dose Apply one mL twice daily topically to the area of desired hair growth.	Orthographic Both names have the modifier "for Women" in the name. Route of Administration Topical Strength Both products have only one strength which may be omitted from the prescription. Dose The dose for both products may be written as UAD (Use as directed).	Orthographic The root names provide sufficient orthographic differences. Frequency of Administration Twice daily vs. every four days

Proposed name: **Oxytrol for Women** **Dosage Form:** **Transdermal System** **Strength:** **3.9 mg per day** **Usual Dose:** **Apply one patch and wear for 4 days in a row; after 4 days remove the used patch and apply a new one.**	**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**
Onxol (Paclitaxel) Concentrate for Injection *Brand name product discontinued; other brands and generics available. 6 mg/mL <u>Usual Dose</u> 135 mg/m^2 to 250 mg/m^2 intravenously over 3 hours every 3 weeks.	<u>Orthographic</u> Both names begin with the letter 'O' and end in the letter string 'ol'. <u>Strength</u> Both products have only one strength which may be omitted from the prescription.	<u>Orthographic</u> Oxytrol contains a downstroke (lower case 'y') and an additional upstroke (lower case 't'). Additionally, Onxol contains 5 letters (as compared to 7 letters in Oxytrol) which causes the name to look shorter when scripted. <u>Dose</u> 135 mg/m^2 to 250 mg/m^2 vs. one patch <u>Frequency of Administration</u> Every 3 weeks vs. every four days

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

/s/

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06/21/2012

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