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--Final

Date:	December 06, 2011
Reviewer(s):	Walter Fava, RPh, MSEd, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Zachary Oleszczuk, PharmD, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	Anturol (Oxybutynin) Gel 3%
Application Type/Number:	NDA 202513
Applicant/sponsor:	Antares Pharma Inc.
OSE RCM #:	2011-2631

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Anturol 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, Anturol, acceptable in OSE Review 2011-1621 dated July 26, 2011.

2 METHODS AND DISCUSSION

For re-assessments of a proposed proprietary name, 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 2011-1621. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names, thought to look or sound similar to Anturol 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 November 25, 2011. OPDP re-eviewed the proposed name on October 6, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Anturol, did not identify any vulnerabilities that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Anturol, 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 Office of Reproductive and Urologic Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

4 REFERENCES

1. OSE Reviews

Fava, W. OSE Review #2011-1621: Proprietary Name Review for Anturol, July 26, 2011.

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/

WALTER L FAVA
12/06/2011

ZACHARY A OLESZCZUK
12/06/2011

CAROL A HOLQUIST
12/06/2011

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
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Proprietary Name Review

Date:	July 26, 2011
Reviewer(s):	Walter Fava, RPh, MSEd, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Carlos Mena-Grillasca, RPh, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
Drug Name(s):	Anturol (Oxybutynin) Gel 3%
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OSE RCM #:	2011-1621

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Anturol, 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 name, Anturol, was previously reviewed by DMEPA during the IND phase and found acceptable in OSE review 2008-1289 dated November 13, 2009.

1.2 PRODUT INFORMATION

Anturol (Oxybutynin) Gel 3% is an antimuscarinic agent indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency. Anturol will be supplied in non-aerosol, metered-dose pump bottles that deliver either 30 or 90 metered pumps and the usual recommended dose is three pumps (84 mg/day) applied once a day. Anturol should be applied to clean, dry, intact skin on the abdomen, or upper arms/shoulders or thighs. Each pump actuation dispenses 0.92 gram (1 mL) of 30 mg/g oxybutynin gel which contains 28 mg oxybutynin. Anturol is stored at room temperature, 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F).

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive and Urologic Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on June 8, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

There are no components of the proposed proprietary name that can contribute to medication error or render the name unacceptable.

2.2.3 FDA Name Simulation Studies

Fifty practitioners participated in DMEPA's prescription studies. Thirty respondents correctly identified the name Anturol with the majority of correct responses occurring in the inpatient and outpatient studies. One respondent in the inpatient study did however identify the name as Anusol. 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, July 1, 2011 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Anturol (see Appendix B). These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines.

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Siderol	FDA	Anafranil	FDA	Adacel	FDA
Astelin	FDA	Analpram-E	FDA	Afrinol	FDA
Lantus	FDA	Antocin	FDA	Ammonul	FDA
Anusol	FDA	Amitone	FDA	Osmitrol	FDA
Ovidrel	FDA	Ed-in-sol	FDA	Anusol HC	FDA
Antivert	FDA	Enterex	FDA	Ontak	FDA
Albuterol	FDA	Centra-Vit	FDA	Antiben	FDA
Androgel	FDA	Enuretrol	FDA	Entsol	FDA
Antara	FDA	Antepar	FDA	Anadrol-50	FDA
Cartrol	FDA	Anaprox	FDA	Cenestin	FDA
Acetasol	FDA	Actonel	FDA	Anaxplex	FDA
Detrol	FDA	Cervidil	FDA	Antabuse	FDA
Anbesol	FDA				

Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Inderal	FDA	Aneurol	FDA	[redacted]	[redacted]
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Antizol	FDA	Hectorol	FDA	Antarol	FDA
Anturan	FDA	Anturane	FDA	[redacted]	[redacted]

Our analysis of the 44 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics for the names. We determined that all 44 names will not pose a risk of confusion as described in Appendix D-E.

DMEPA communicated these findings to the Division of Reproductive and Urologic Products via e-mail on June 13, 2011. At that time we also requested additional information or concerns that could inform our review. The Division of Reproductive and Urologic Products provided no additional concerns with the proposed proprietary name, Anturol.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

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

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name, Anturol, will be re-reviewed 90 days prior to approval of the NDA. If we find the name acceptable following the re-review, we will notify you.

If any of the proposed product characteristics as stated in your May 5, 2011 submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

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.

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

12. ***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.

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

16. ***Medical Abbreviations Book***

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by DDMAC. DDMAC 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. DDMAC 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 product characteristics considered for this review appears in Appendix B1 of this review.

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).

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*
	Similar spelling	Identical prefix	• Names may appear similar

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

Look-alike		Identical infix Identical suffix Length of the name Overlapping product characteristics	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 Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DDMAC'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 characteristics listed in Appendix B1 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***

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

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

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

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

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

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

product 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, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Upper case 'A'	'O', 'H', 'T', 'U', 'Ce', 'Ci', 'Cl',	any vowel
lower case 'n'	'r', 'u', 'v', 'w'	'm'
lower case 't'	'l', 'x'	'd'
lower case 'u'	'n', 'a', 'e', 'i', 'o'	any vowel
lower case 'r'	'n', 's', 't', or 'v'	'w'
lower case 'o'	'a', 'c', 'u', or 'v'	any vowel
lower case 'l'	'e', 'i', or 't'	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Anturol Study (Conducted on 05/20/2011)

(b) (4)

FDA Prescription Simulation Responses.

Study Name: Anturol

		85 People Received Study 50 People Responded
Study Name: Anturol		
INPATIENT	**VOICE**	**OUTPATIENT**
ANTROL (1)	ANTAROL (1)	ANTAROL (1)
ANTUROL (15)	ANTERAL (3)	ANTURAL (1)
ANUSOL (1)	ANTERALL (1)	ANTUROL (14)
ARITUROL (1)	ANTEROL (7)	AUTUROL (1)
	ANTUROL (1)	
	ANTTAROL (1)	
	ANTURAL (1)	

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 Anturol	Failure preventions
Antarol	Propranolol	Look and Sound	Proprietary name commercially marketed in Hong Kong and Ireland
Antepar	Piperazine Citrate	Look	Discontinued product for which no generic equivalent is available.
Antocin	Atosiban	Look	Approval denied by FDA in 1998. Product not commercially marketed
Afrinol	Pseudoephedrine	Look	No commercially marketed drug product is available under this proprietary name. Confirmed this information with Schering Plough.

Enuretrol		Look	No additional information found. Name identified in MicroMedex version 1.0 but name not found in MicroMedex version 2.0 which is the only currently available version to search.
Enterex	Enteral tube feeding supplement	Look	Lacks convincing orthographic similarity to Anturol and is not likely to be confused with Anturol considering the setting of use (Anturol would be self-administered vs Enterex which would be administered by a healthcare professional or a caregiver through an NG tube).
Centra-Vit	Multivitamin	Look	Lacks convincing orthographic similarity to Anturol and is an over the counter multiple vitamin.
Aneurol	Diazepam	Sound	Foreign proprietary name commercially marketed in Spain.
Siderol	Multivitamin/mineral supplement	Look	No product information available in major drug references or via Google searches.
Cartrol	Carteolol	Look	Discontinued product for which no therapeutic equivalent is available

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: **Anturol** **(Oxybutynin) Gel**	**Strength(s):** **3%**	**Usual dose:** **3 pumps topically once a day**
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode**
Anturane or Anturan (Sulfinpyrazone) 200 mg and 400 mg capsules Usual dose: 200 mg to 400 mg daily in divided doses	Orthographic similarities include both names begin with the letters, 'Antur'.	Orthographic difference: The ending letters, 'ane' in Anturane look different from the ending letters, 'ol' in Anturol when scripted. Anturane is a multiple strength product therefore prescribers will need to indicate a strength on prescriptions for Anturane which will help differentiate it from Anturol since there is no strength overlap between this name pairs (3% vs 200 mg or 400 mg). Anturol is a topical gel vs Anturane which is an oral capsule. Anturol has a single strength (3%) vs Anturane which has mulitple strengths (200 mg and 400 mg). Unit of measure for Anturol is % compared to milligrams for Anturane.
Lantus (Insulin Glargine) 100 units/mL Solution for Injection	Orthographic similarities include both names containing the letter string 'ant'.	Orthographic difference: In the name Lantus, the beginning letter 'L' precedes the letter string 'ant' which Anturol does not have and may help differentiate this name pair when scripted. Anturol is applied topically once a day and is prescribed/ordered by the number of pumps of gel to apply, whereas Lantus is prescribed/ordered by the number of units to inject subcutaneously.

Ovidrel (Human Chorionic Gonadotropin) 250 mcg Powder for Injection 250 mcg/0.5 mL Prefilled Syringe for injection Usual dose: Males 1 to 5 years of age: 500 Units intramuscularly two times per week for 5 weeks. Infants (6 to 12 months) 250 Units intramuscularly two times per week for 5 weeks.	Orthographic similarities include the beginning letter, 'A' in Anturol may look similar to the beginning letter, 'O' in Ovidrel and both names have an upstroke letter ('t' vs 'd') in the middle of the name and end in the upstroke letter, 'l'.	Orthographic difference: The beginning letter string, 'Ant' in Anturol looks different from the beginning letter string, 'Ovid' in Ovidrel when scripted. Ovidrel is administered via intramuscular or subcutaneous injection twice a week for 5 weeks vs Anturol which is administered topically once a day.
Antivert (meclizine) 12.5 mg, 25 mg, and 50 mg Tablet Usual dose: 25 mg to 50 mg by mouth one hour before traveling. May repeat every 24 hours as needed.	Orthographic similarities include both names beginning with the letters, 'Ant' and ending in an upstroke letter, ('l' vs 't').	Orthographic difference: The ending letter string, 'urol' in Anturol looks different from the ending letter string, 'vert' when scripted and may help differentiate the name pair. Antivert is available in multiple strengths so practitioners would need to prescribe/order by indicating a strength and it has no strength overlap with Anturol. Units of measure for Anturol is % vs milligrams for Antivert. Frequency of administration is once a day for Anturol vs one time before travel and repeat in 24 hours as needed.

Albuterol 0.09 mg/actuation Inhalation Aerosol Usual dose: Inhale 4 to 8 inhalations by mouth every 20 minutes for up to 4 hours, then every 1 to 4 hours as needed 2 mg/5 mL Oral Syrup Usual dose: Take one to two teaspoonsful by mouth three to four times a day 2 mg and 4 mg Tablet Usual dose: Take one tablet by mouth three to four times a day. 4 mg and 8 mg Extended-Release Tablet Usual dose: Take one tablet by mouth every 12 hours.	Orthographic similarities: Both names begin with the letter, 'A' and ending in the letters, 'rol'. Both names also contain the cross stroke letter, 't'.	Orthographic differences: Albuterol contains 9 letters and has a different length and shape with scripted compared to the 7 letters in Anturol. The beginning letter string, 'Alb' in Albuterol has three upstroke letters compared to two upstroke letters, 'A' and 't' in Anturol. Anturol is a single strength (3%) vs Albuterol which has multiple strengths (0.09 mg/actuation, 2 mg/5 mL, 2 mg and 4 mg) Anturol is a topical gel vs Albuterol which is available as an inhalation solution, oral syrup, and as tablets. Albuterol is dosed multiple times a day compared to once a day dosing for Anturol.
Androgel (Testosterone) Gel 1% Usual dose: Apply 5 grams once a day (preferably in the morning) to clean, dry, intact skin of the shoulders, and/or upper arms or to the abdomen	Orthographic similarity stems from both names beginning with the letters, 'An' and having an upstroke letter in the third position, ('t' vs 'd'). Both names also end in the upstroke letter, 'l'.	Orthographic difference: Anturol contains the cross stroke letter, 't' which Androgel does not have. In addition, Androgel has a downstroke letter, 'g', which Anturol does not have. The combination letters within the infix for Androgel, '-rog-' gives the name a much longer appearance when scripted than that of the proposed name Anturol.
Antara (Fenofibrate) 43 mg and 130 mg capsules Usual dose: Once capsule by mouth daily.	Orthographic similarities include both names beginning with the letters, 'Ant'.	Orthographic difference: Anturol ends in the upstroke letter, 'l' which Antara does not have. Antara is avaible in multiple strengths therefore practitioners would have to indicate a strength on prescription orders for Antara and there is no strength overlap between Antara and Anturol. Anturol is a topical gel compared to Antara which is an oral capsule. Anturol would be ordered as 'Apply 3 pumps to skin once a day' vs Antara which would be ordered as 'Take one capsule by mouth once a day'.

Acetasol (Acetic Acid, Glacial) 2% Otic Solution Usual dose: Instill 4 to 6 drops into external auditory canal every 2 to 3 hours.	Orthographic similarities: Both names have the upstroke letters, 'A', 't', and 'l' in similar positions in the names.	Despite orthographic similarities, differentiating product characteristics will help to differentiate this name pair. Anturol is a gel vs Acetasol which is an otic solution Anturol is applied topically to either the arms, abdomen, or thighs vs Acetasol which is instilled into the ear Anturol is dosed once a day vs Acetasol which is dosed every 2 to 3 hours.
Detrol (Tolterodine Tartrate) 1 mg, 2 mg Tablet Usual dose: Take 2 mg by mouth twice a day Detrol LA: 2 mg and 4 mg extended-release tablet Usual dose: Take 4 mg by mouth once a day	Orthographic similarities: Both names end in the letters, 'rol'.	Orthographic difference: Anturol has 7 letters and appears longer when scripted compared to the 6 letters in Detrol. Anturol is a gel vs Detrol which is a tablet Anturol is applied topically vs Detrol which is taken orally. Anturol is dosed as '3 pumps' vs Detrol which is dosed in milligrams. Anturol is single strength (3%) vs Detrol which is multiple strength (1 mg and 2 mg).
Anbesol (Benzocaine) 10% topical dental gel 10% topical dental solution 7.5% topical dental gel 20% topical dental gel 20% topical dental solution	Orthographic similarities: Both names begin with the letters, 'An' and have an upstroke letter, 't' vs 'b' in the third position. Both names also end in the letters, 'ol'.	Orthographic differences: Anturol has the cross stroke letter, 't' which Anbesol does not have. Additionally, Anbesol has the letter, 's' which Anturol does not have and may help differentiate the names when scripted. Anturol is a topical gel applied as three pumps to the skin once a day compared to the different topical forms of Anbesol which are applied as thin layers to the affected area(s) as needed. Anturol is only available in one strength (3%) and does not have any overlap or acheivable doses with Anbesol (7.5%, 10%, 20%).

Actonel (Risedronate) 5 mg, 35 mg, 75 mg, and 150 mg tablet Usual dose is one tablet by mouth once a day (5 mg and 35 mg) or once a week (75 mg) or once a month (150 mg) depending on the strength prescribed.	Orthographic similarities: Both names begin with the letter, 'A' and have the cross stroke letter, 't' and upstroke letter, 'l' in the same positions.	Orthographic differences: Actonel has the letter, 'c' in the second position which Anturol does not have and the common letter, 'n' between the names appears in different positions within the names which may help differentiate these names orthographically when scripted. Anturol is a topical gel vs Actonel which is a tablet Anturol is applied topically vs Actonel which is administered orally. Anturol is administered once a day vs Actonel which has different frequencies of administration depending on the product strength. Anturol is a single strength product (3%) vs Actonel which has multiple strengths (5 mg, 35 mg, 75 mg, 150 mg). The unit of measure for Anturol is % compared to milligrams for Actonel.
Adacel (Diphtheria/Tetanus Toxoid; Pertussis) Vaccine Usual dose: Inject 0.5 mL intramuscularly x 1 dose at least every 10 years	Orthographic similarities: Both names begin with the letter, 'A' and end with the letter, 'l'.	Orthographic differences: Anturol has the cross stroke letter, 't' which Adacel does not have and may help differentiate the names when scripted. Anturol is a gel vs Adacel with is an injection Anturol is applied topically vs Adacel which is injected intramuscularly Anturol is administered once a day vs Adacel which is administered one time
Ammonul (Sodium Benzoate and Sodium Phenylacetate) 10%/10% Injection Usual dose: 5.5 g/m^2 infused intravenously over 90 to 120 minutes through a central line as needed over 24 hours until plasma ammonia concentrations normalize.	Orthographic similarities: Both names begin with the letter, 'A' and end in the letter, 'l'.	Orthographic differences: Anturol has the cross stroke letter, 't' in the third position which also provides an upstroke which Ammonul does not have. Anturol is a gel vs Ammonul which is an injection Anturol is applied topically vs Ammonul which is administerd intravenously Anturol is dosed as 'pumps' vs Ammonul which is dosed in milligrams

Osmitrol (Mannitol) 5%, 10%, 15%, 20 % Injection Usual dose: 10% to 20% administered as a continuous intravenous infusion at a rate of 25 mL to 75 mL/hour.	Orthographic similarities include both names end in the letters, 'rol' and the beginning letter, 'A' in Anturol may look like the beginning letter, 'O' in Osmitrol when scripted. Both names also contain the cross stroke letter, 't' in the name.	Orthographic differences include the letter string, 'smi' in Osmitrol looks different from the corresponding letter string, 'ntr' in Anturol. In addition, Osmitrol has the letters 's' and 'm' which Anturol does not have and it appears longer than Anturol when scripted. Anturol is a gel vs Osmitrol which is an injection. Anturol is single strength (3%) vs Osmitrol which is multiple strengths (5%, 10%, 15%, and 20%). Anturol is administered topically vs Osmitrol which is administered intravenously. Anturol is dosed as 'pumps' vs Osmitrol which is dosed as '25 mL/hour to 75 mL/hour'.
Anusol (Pramoxine and Zinc Oxide) 1%/12.5% Ointment Usual dose: Apply a small amount to the affected area up to five times a day.	Orthographic similarities include both names beginning with the letters, 'An' and ending in the letters, 'ol'.	Orthographic differences: Anturol has the cross stroke letter, 't' which Anusol does not have. In addition, Anturol has three upstroke letters, 'A', 't', and 'l' which gives it a different shape when scripted compared to Anusol which has two upstroke letters, 'A' and 'l'. Anturol is dosed as 'pumps' vs Anusol which is dosed as 'small amount'. Anturol is applied to the upper arms, abdomen or thighs vs Anusol which is applied rectally. Anturol is applied once a day vs Anusol which is applied up to five times a day. 'Anusol' is marketed under the proprietary name, 'Tucks'. Considering the orthographic similarity between the names and the response of 'Anusol' in our Rx study, we evaluated a worst case scenario for orders written: 'Anusol Use as directed' vs Anturol Use as directed', drug usage data from 2008 to present does not support frequent prescribing of Anusol with the directions 'use as directed'. The medical officer from DRUP also stated that Anturol orders are likely to include instructions that tell patients how many pumps to apply to their skin each day.
Anusol HC (Hydrocortisone) 1% and 2.5% cream 25 mg suppository	Orthographic similarities: Both names begin with the letters, 'An' and have the letters, 'ol' in similar positions.	Anusol HC has a suffix, 'HC' which may help differentiate the name pair. Anturol is single strength (3%) vs Anusol HC which is multiple strengths (1% , 2.5%, and 25mg). Anturol is dosed as 'pumps' vs Anusol HC which is dosed as either 'small amount' or 'one suppository'. Anturol is applied once a day vs Anusol HC which is applied twice a day as needed.

Ontak (Denileukin Diftitox) 150 mcg/mL Injection Usual dose: 9 mcg/kg/day administered intravenously over 15 minutes for 5 days.	Orthographic similarities: Both names contain the letters, 'n' and 't' in the second and third positions and the beginning letter, 'A' in Anturol may look like the beginning letter, 'O' in Ontak when scripted.	Orthographic differences: Ontak ends in the letter 'k' which looks different from the ending letter, 'l' in Anturol. The letter string, 'turol' in Anturol looks different from the letter string, 'tak' in Ontak when scripted. Anturol is a gel vs Ontak which is an injection. Anturol is applied topically vs Ontak which is administered intravenously. Anturol is dosed as 'pumps' vs Ontak which is dosed as micrograms. Anturol is applied once a day vs Ontak which is administered over 15 minutes once a day for 5 days. Unit of measure for Anturol is '%' compared to 'micrograms' for Ontak.
Antiben (Antipyrine and Benzocaine) 54 mg/ml – 14 mg/mL Otic Solution Usual dose: Instill 2 to 4 drops into ear canal three to four times a day.	Orthographic similarities: Both names contain seven letters and begin with the letters, 'Ant'.	Orthographic differences: Anturol ends in the upstroke letter, 'l' compared to Antiben which ends with the letter, 'n'. The spacing of the three upstroke letters, 'A', 't', and 'l' is different from the spacing of the upstroke letters, 'A', 't', and 'b' in Antiben, which gives the names different shapes when scripted. Anturol is a gel vs Antiben which is an otic solution Anturol is applied topically vs Antiben which is instilled in the ears. Anturol is dosed as 'pumps' vs Antiben which is dosed as drops. Anturol is applied once a day vs Antiben which is instilled three to four times a day as needed. Unit of measure for Anturol is '%' compared to milligrams/milliter for Antiben.
Entsol (Hypertonic Sodium Chloride) Nasal Gel 1.1% 3% Nasal Spray Usual dose: Gel: Apply to each nostril once a day Spray: Spray one squirt in each nostril once a day	Orthographic similarities: Both names have the letters, 'n' and 't' in the second and third positions in the names and end in the letters, 'ol'. The beginning letter, 'E' may appear similar to the beginning letter, 'A' when scripted in lower case.	Orthographic differences: Entsol contains six letters and appears shorter when scripted compared to seven letters in Anturol. The letter string, 'so' in Entsol looks different from the letter string, 'ur' when scripted. Anturol is applied to the abdomen, upper arms, or thighs vs Entsol which is applied intranasally. Anturol is dosed as 'pumps' vs Entsol which is dosed as 'small amount' or as 'sprays'.

Anadrol-50 (Oxymetholone) 50 mg Tablet Usual dose: 1 mg/kg to 2 mg/kg (up to 5 mg/kg) orally once a day	Orthographic similarities: Both names contain seven letters, begin with the letters, 'An' and end in the letter, 'l'.	Orthographic differences: Anadrol-50 has the numerical suffix, '50' which will help differentiate it from orders for Anturol. Anturol is available as a topical gel compared to Anadrol-50 which is available as a 50 mg tablet. Anturol is administered topically compard to Anadrol-50 which is administered orally. Anturol has '%' unit of measure compared to milligrams for Anadrol-50.
Anaprox (Naproxen) 275 mg Tablet Usual dose: Take one to two tablets by mouth twice a day	Orthographic similarities: Both names contain seven letters and begin with the letters, 'An'.	Orthographic differences: Anaprox has one downstroke letter ('p') and one upstroke letter ('A') compared to no downstroke and three upstroke letters, 'A', 't', and 'l' in Anturol. Anturol is a gel vs Anaprox which is a tablet. Anturol is applied topically vs Anaprox which is administered orally. The unit of measure for Anturol is '%' compared to milligrams for Anaprox. Anturol is dosed once a day compared to twice a day for Anaprox.
Cenestin (Conjugated Estrogen) 0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, and 1.25 mg Usual dose: One tablet by mouth once a day.	Orthographic similarities: The beginning letter, 'A' in Anturol may look similar to the beginning letter, 'C' in Cenestin when scripted.	Orthographic differences: Anturol contains three upstroke letters, 'A', 't', and 'l' compared to two upstroke letters, 'C' and 't' in Cenestin. The 't' in Anturol appears in the middle of the name compared to the 't' in Cenestin which appears toward the end of the name. Anturol is a gel vs Cenestin which is a tablet. Anturol is applied topically vs Cenestin which is administered orally. Anturol is available as one strength (3%) compared to multiple strengths of Cenestin (0.3 mg, 0.45 mg, 0.635 mg, 0.9 mg, and 1.25 mg), therefore, doctors will need to indicate a strength on orders for Cenestin. Anturol has '%' unit of measure compared to milligrams for Cenestin.

Cervidil (Dinoprostone) 10 mg vaginal insert Usual dose: One 10 mg insert placed in cervical canal. Remove at onset of labor or 12 hours after insertion.	Orthographic similarities: The beginning letter, 'A' in Anturol may look similar to the beginning letter, 'C' in Cervidil when scripted. In addition, both names end in the letter, 'l'.	Orthographic differences: The upstroke letter pattern in Cervidil is different compared to Anturol and has a different shape when scripted. In addition, Anturol has the cross stroke letter, 't' which Cervidil does not have. Anturol is a 3% gel compared to Cervidil which is a vaginal insert. Anturol is applied topically once a day compared to Cervidil which is inserted intravaginally one time at the onset of labor. Anturol has a % unit of measure compared to milligram unit of measure for Cervidil.
Antabuse (disulfiram) 250 mg and 500 mg tablet Usual dose: 500 mg by mouth once a day	Orthographic similarities: Both names begin with the letters, 'Ant' and have an upstroke letter, ('t' vs 'b') in the middle of the name.	Orthographic differences: Antabuse contains eight letters compared to seven letters in Anturol and appears longer when scripted. Anturol is a gel vs Antabuse which is a tablet. Anturol is applied topically vs Antabuse which is administered orally. Anturol is dosed as 'pumps' vs Antabuse which is dosed as tablets or milligrams. Anturol is available as a single strength (3%) compared to Antabuse which is available in two strengths (250 mg and 500 mg). Therefore practitioners will need to indicate a strength on orders for Antabuse which will help to differentiate this name pair. Unit of measure for Anturol is '%' vs milligrams for Antabuse.
Anaplex DM (Brompheniramine, Pseudoephedrine, and Dextromethorphan) 4 mg/30 mg/60 mg/5 mL Usual dose: Take 5 mL (one teaspoonful) by mouth every 4 to 6 hours as needed.	Orthographic similarities: Both names begin with the letters, 'An' and have the overlapping letter, 'l'.	Orthographic differences: Anaplex DM has the modifier, 'DM' which helps differentiate it from Anturol. In addition, Anturol ends in the upstroke letter, 'l' compared to the root name, Anaplex which has the upstroke letter, 'l' infixed in the middle of the name and ends in the letter, 'x'. Anturol is a gel vs Anaplex DM which is an oral liquid. Anturol is applied topically vs Anaplex DM which is administered orally. Anturol is dosed as 'pumps' vs Anaplex DM which is dosed as teaspoonsful or 5 mL. Anturol is administered once a day vs Anaplex DM which is administered every 4 to 6 hours as needed.

Anafranil 25 mg, 50 mg and 75 mg Capsule Usual dose: 100 mg by mouth in divided doses	Orthographic similarities: Both names begin with the letter, 'A' and end in the letter, 'l'. Both names have the letter, 'n' in the second position and have an upstroke letter, ('t' vs 'f') in the middle of the name.	Orthographic differences: Anturol has seven letters and appears shorter when scripted compared to the nine letters in Anafranil. Anturol is a gel vs Anafranil which is a capsule. Anturol is applied topically vs Anafranil which is administered orally. Anturol is applied once a day vs Anafranil which is dosed twice a day. Anturol is single strength (3%) vs Anafranil which has multiple strengths (25 mg, 50 mg, and 75 mg). Anturol is dosed as 'pumps' vs Anafranil which is dosed as either milligrams or capsules.
Analpram-E (Pramoxine and Hydrocortisone) 1%/2.5% Cream Usual dose: Apply to affected area three to four times daily	Orthographic similarities: Both names begin with the letter, 'A' and contain the letter, 'l'.	Orthographic differences: Anturol has the cross stroke letter, 't' which Analpram-E does not have. Analpram-E also contains nine letters and appears longer with a different shape due to the downstroke letter, 'p' when scripted compared to seven letters in Anturol which does not have any downstroke letters. The modifier, 'E' in Analpram-E may also help differentiate it from Anturol when scripted. Anturol is dosed as 'pumps' vs Analpram-E which is dosed as a 'small amount'. Anturol is applied once a day compared to Analpram-E which is applied three to four times a day.
Amitone (Calcium Carbonate) 500 mg tablet Take one tablet by mouth one to three hours after meals and at bedtime.	Orthographic similarites include both names begin with the letter, 'A' and have the letter, 't' in similar positions in the names.	Orthographic differences: Anturol ends with an upstroke letter, 'l' which Amitone does not have and the ending letter string, 'rol' in Anturol looks different from the ending letter string, 'one' in Amitone. Anturol is a gel vs Amitone which is a tablet. Anturol is administered topically vs Amitone which is administered orally. Anturol is dosed as 'pumps' vs Amitone which is dosed as milligrams or tablets. Anturol is administered once a day vs Amitone which is administered four times a day. Unit of measure for Anturol is '%' vs milligrams for Amitone.

Ed-in-sol (Ferrous Sulfate) 75 mg/0.6 mL drops Usual dose: 2 mg to 4 mg/kg/day by mouth in every 12 to 24 hours.	Orthographic similarities: Both names contain seven letters and end in the letters, 'ol'. The beginning letter, 'E' in Ed-in-sol may look similar to the beginning letter, 'A' in Anturol when scripted in lower case ('e' vs 'a').	Orthographic differences: Anturol has a shorter distance between the upstroke letters, 't', and 'l', compared to the distance between the upstroke letters, 'd' and 'l' in Ed-in-sol, providing a different shape between the name which may help differentiate them when scripted. Anturol is a gel vs Ed-in-sol which is available as drops (concentrated oral solution). Anturol is administered once a day vs Ed-in-sol which is administered once or twice a day. Anturol is dosed as 'pumps' vs Ed-in-sol which is dosed as drops or milligrams or dropperful. Unit of measure for Anturol is '%' vs mg/mL for Ed-in-sol.
Astelin (Azelastine) 137 mcg/actuation Usual dose: One to two sprays per nostril twice a day.	Orthographic similarities: Both names contain seven letters, begin with the letter, 'A', and have the letter, 't' in the third position of the name.	Orthographic differences: Anturol ends in the upstroke letter, 'l' compared to Astelin which ends in the lower case letter, 'n'. Anturol is a gel vs Astelin which is an inhalation solution. Anturol is applied topically vs Astelin which is applied intranasally. Anturol is administered once a day compared to Astelin which is administered twice a day.
Inderal (Propranolol) 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg immediate release tablets Long Acting (LA): 60 mg, 80 mg, 120 mg and 160 mg capsules 1 mg/mL injection 4 mg/mL and 8 mg/mL oral solution 80 mg/mL Concentrated oral solution	Orthographic similarities: Both names contain seven letters and appear similar in length and shape when scripted. In addition they share the letters, 'n' and 'l' in the second and last positions. Phonetic similarities: Both names contain three syllables and have similar sounding second and third syllables, 'urol' in Anturol vs 'eral' in Inderal.	Orthographic differences: The beginning letter, 'A' in Anterol looks different from the beginning letter, 'I' in Inderal when scripted. Anturol is a gel vs Inderal which is a tablet, capsule, injection, or solution. Anturol is applied topically vs Inderal which is administered orally or intravenously. Anturol is single strength (3%) vs Inderal which is multiple strengths (10 mg, 20 mg, 40 mg, 60 mg, 80 mg, 90 mg, 1 mg/mL, 4 mg/mL, 8 mg/mL, and 80 mg/mL). Anturol is dosed as 'pumps' vs Inderal which is dosed as 'milligrams', or capsules or tablets, or 'milliliters'. Unit of measure for Anturol is '%' vs 'mg' or 'mg/mL' for Inderal.

Antizol (Fomepizole) 1 gram/mL Injection Usual dose: 15 mg/kg administered intravenously as a loading dose followed by 10 mg/kg every 12 hours for 4 doses, then 15 mg/kg every 12 hours until ethylene glycol or methanol serum levels are undetectable or <20 mg/dl	Orthographic similarities: Both names have seven letters and begin with the letters, 'Ant' and end with the letters, 'ol'. Phonetic similarities: Both names contain three syllables and have identical first and last syllables.	Orthographic differences: Antizol has the lower case letter, 'z' which Anturol does not have and may provide a downstroke depending on how it is scripted. Anturol is a gel vs Antizol which is an injection Anturol is applied topically vs Antizol which is administered intravenously. Anturol is dosed as 'pumps' vs Antizol which is dosed as milligrams. Anturol is administered once a day vs Antizol which is administered every 12 hours. Antizol would be used in an inpatient and emergency room setting for cases of ethylene glycol ingestion/poisoning.
Hectorol (Doxercalciferol) 0.5 mcg, 1 mcg, 2.5 mcg capsule 2 mcg/mL Injection Usual dose: Capsule: 2.5 mcg by mouth three times a week Intravenous: 4 mcg intravenously as a bolus injection three times a week at the end of dialysis	Orthographic similarities: Both names end in the letters, 'rol' and have the letter, 't' in the middle of the name. The beginning letter, 'A' in Anturol may look similar to the letter, 'H' in Hectorol when scripted.	Orthographic differences: The lower case letter, 'n' in Anturol provides orthographic differentiation from the corresponding letters, 'ec' in Hectorol. Anturol is a gel vs Hecterol which is a capsule or injection. Anturol is applied topically vs Hectorol which is administered orally or intravenously. Anturol is dosed as 'pumps' vs Hectrol which is dosed as micrograms. Anturol is administered once a day compared to Hectorol which is administered three times a week. Unit of measure for Anturol is % compared to micrograms or micrograms/milliliter for Hecterol.

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