CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204977Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	June 3, 2013
Reviewer:	Reasol S. Agustin, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, MS, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Omtryg (omega-3-acid ethyl esters), 900 mg
Application Type/Number:	NDA 204977
Applicant/Sponsor:	Trygg Pharma, Inc
OSE RCM #:	2013-651

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

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant, Trygg Pharma, Inc. submitted a request for review of the proposed proprietary name, Omtryg for Omega-3-acid ethyl esters, on March 8, 2013 as part of NDA 204977.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 8, 2013 proprietary name submission.

- Active Ingredient: Omega-3-acid ethyl esters
- Indication: Adjunct to diet to reduce (b) (4) triglyceride levels (≥500 mg/dL) in adult patients with severe hypertriglyceridemia.
- Route: Oral
- Dosage Form: Soft gel capsules
- Strengths: 900 mg (1 capsule contains a minimum of 900 mg of omega-3 acid ethyl esters)
- Dose and Frequency: 4 capsules daily; may be taken as 4 capsules once daily or as 2 capsules twice daily
- How Supplied: Bottles of 120
- Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not freeze. Keep out of reach of children.
- Container and Closure: White opaque high density polyethylene (HDPE) 400 mL bottle with a (b) (4) white opaque (b) (4) screw cap.

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The March 15, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Omtryg, was derived from blank canvas and is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. The Applicant did not indicate that the components of the proposed name "Om" and "Tryg" makes reference to the active ingredient (Omega) and the applicant's company name (Trygg Pharma, Inc). However, we note that the proposed name utilizes part of the applicant's name. Although acceptable for this product, use of the suffix 'Tryg' may affect the acceptability of future proprietary name proposals that contain 'Tryg' in the name. This will be communicated to the Applicant.

2.2.3 FDA Name Simulation Studies

Seventy practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Two of the 23 inpatient participants responded correctly and the most common misinterpretation occurred with 14 participants misinterpreting the letter 'm' for 'n' (i.e. O***M***tryg misinterpreted as 'O***N***tryg' n=7). None of the 25 voice participants responded correctly and a common misinterpretation occurred with 17 participants misinterpreting the letter 'y' for '' (i.e. tr***Y***g misinterpreted as 'tr***I***g'). Six of the 23 outpatient participants responded correctly and the most common misinterpretation occurred with 10 participants misinterpreting the letter 'm' for 'ni' (i.e. O***M***tryg misinterpreted as 'O***NI***tryg n=7). These misinterpretations were considered in our name assessment (see Appendix B). See Appendix C for the complete listing of interpretation from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 21, 2013 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

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

disciplines. Table 1 also includes the names identified by (b) (4) (b) (4) not identified by DMEPA and requires further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, Expert Panel Discussion (EPD), Other Disciplines, and External Name Study)

Name	*Source*	*Name*	*Source*	*Name*	*Source*
Look Similar					
Omacor	(b) (4)	Omeprazole	(b) (4)	Omnaris	(b) (4) /EPD
Omnitrope	(b) (4)	Omontys	(b) (4) /EPD	Onglyza	(b) (4) /EPD
Zomig	(b) (4)	Ultrex	(b) (4)	Cometriq	SE
Actiq	EPD	Qutenza	EPD	Amitiza	EPD
Omnitarg***	EPD	(b) (4) ***	SE	Amaryl	EPD
Avitene/ Avitene Flour	SE	Ambenyl D/ Ambenyl Cough	EPD	Amdry-D/ Amdry-C	EPD (b) (4)
Oravig	EPD	Androxy	EPD	Ondrox	EPD
Antagon	EPD	Antrypol	EPD	Ornidyl	EPD
Ontak	SE	Artane	SE	Atryn	DSI
Look and Sound Alike					
Entereg	EPD	Emtriva	(b) (4)		

Our analysis of the thirty-two names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 32 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on April 26, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on April 29, 2013, they stated no objections with the proposed proprietary name, Omtryg.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Omtryg, and have concluded that this name is acceptable. We note that your proposed name utilizes part of the name *Trygg Pharma*. Although acceptable for this product, use of the suffix 'Tryg' may affect the acceptability of future proprietary name proposals that contain 'Tryg' in the name.

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your March 8, 2013 submission are altered, the name must 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. This database also lists the orphan drugs.

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. ***Rx List (www.rxlist.com)***

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

19. ***Dogpile (www.dogpile.com)***

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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 Identical infix Identical suffix Length of the name	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or

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

Look-alike		Overlapping product characteristics	electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if

any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

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

Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity 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.

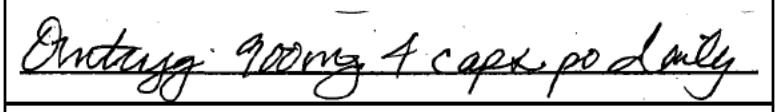
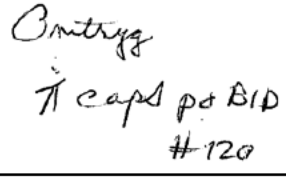
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Omtryg	Scripted May Appear as	Spoken May Be Interpreted as
'O'	Q, A, D	Oh, Ah, Uh, E
lowercase 'o'	a, c, e, u	oh, ah, uh
lowercase 'm'	rn, nn, n, ni, v, w, wi, vi, onc, z	b, n, p
lowercase 't'	r, f, x, l	D
lowercase 'r'	s, n, e, v, u, i	
lowercase 'y'	f, p, u, v, x, z, g	e, i, u
lowercase 'g'	q, j, s, z	k, j, gue
Letter Strings		
'tr'	h, b	
'ry'	ij	ri
'yg'	gg	eague, eeg, ique, ig, ige
ryg	igg, rij, rej	reak

Appendix C: Prescription Simulation Samples and Results

Figure 1. Omtryg Study (Conducted on *March* 22, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Omtryg 2 capsules by mouth twice daily #120
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Omtryg

As of Date 4/11/2013

191 People Received Study

70 People Responded

Study Name: Omtryg

Total	22	25	23	70
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
???	1	0	0	1
AMTRIG	0	2	0	2
AMTRIGUE	0	2	0	2
ANITRYG	0	0	1	1
ANTRIGUE	0	1	0	1
EMTREAK	0	1	0	1
EMTRIGE	0	1	0	1
ILLEGIBLE	1	0	0	1
OBTREGE	0	1	0	1
OBTRIGE	0	1	0	1
OBTRIGUE	0	2	0	2
OINTRYG	1	0	0	1
OMITRIYG	0	0	1	1
OMITRYG	0	0	5	5
OMTREAGUE	0	1	0	1
OMTREEG	0	1	0	1
OMTREGUE	0	1	0	1
OMTRIG	0	1	0	1

OMTRIGUE	0	1	0	1
OMTRIQUE	0	2	0	2
OMTRYG	2	0	6	8
ONITRIG	0	0	1	1
ONITRYG	0	0	7	7
ONITRYZ	0	0	1	1
ONTAGG	1	0	0	1
ONTAYG	1	0	0	1
ONTIYG	1	0	0	1
ONTREE	0	1	0	1
ONTRIJG	2	0	0	2
ONTRIZG	1	0	0	1
ONTRYG	7	0	1	8
ONTUZG	1	0	0	1
OPTRIG	0	1	0	1
ORNTRIYG	1	0	0	1
ORNTRYG	1	0	0	1
ORNTUGG	1	0	0	1
UMTRIEGE	0	1	0	1
UMTRIGE	0	1	0	1
UMTRIGUE	0	2	0	2
UNTRIG	0	1	0	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 Omtryg	Failure preventions
1	**Omnitrope**	Somatropin	Look alike	The pair have sufficient orthographic differences
2	**Zomig**	Zolmitriptan	Look alike	The pair has sufficient orthographic differences.
3	**Qutenza**	Capsaicin	Look alike	The pair have sufficient orthographic differences
4	**Onglyza**	Saxagliptin	Look alike	The pair have sufficient orthographic differences
5	**Amaryl**	Glimepiride	Look alike	The pair have sufficient orthographic differences
6		**Omeprazole**	Look-alike	The pair have sufficient orthographic differences
7	**Ultrex**	Benzalkonium Chloride	Look alike	The pair have sufficient orthographic differences
8	**Omnitarg**[***]	Pertuzumab	Look and sound alike	Proposed Proprietary Name found unacceptable by DDMAC (currently Office of Prescription Drug Promotion (OPDP) in OSE# 2007-628, dated March 29, 2007. Product approved under new proprietary name Perjeta.
9	**Ornidyl**	Eflornithine HCl	Look alike	Orphan drug. No pending NDA or commercial IND within the agency
10	(b) (4)	Levonorgestrel and Ethinyl Estradiol	Look alike	Proposed Proprietary Name found unacceptable by DMEPA in OSE #2011-1107 and #2011-1109, dated May 15, 2012. Proprietary name request was withdrawn by the Applicant on October 12, 2012. Applicant will market product under the established name.

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

11	(b) (4)			
12	**Ondrox**	Nutritional agent and Vitamins	Look alike	Name identified in Clinical Pharmacology database. Unable to find product characteristics in commonly used drug databases.
13	**Omacor**	Omega-3-acid ethyl esters	Look-alike	The proprietary name, Omacor is currently marketed as Lovaza. The Sponsor was asked to change the name due to medication errors with a currently marketed product Amicar. Omacor was changed to Lovaza in OSE #2007-704 dated May 1, 2007.

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: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1	**Actiq** (Fentanyl Citrate) **Dosage Form and Strength:** Oral Buccal Lollipop: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg **Usual dose:** 2 doses (up to 800 mcg/dose) per individual breakthrough pain episode	**Orthographic similarity:** The beginning letters 'O' and 'A' and ending letter 'g' and 'q' appear orthographically similar when scripted. In addition, both names contain an upstroke 't' in similar positions. **Dosage form and route of administration:** Both are available as oral dosage forms	**Orthographic difference:** Omtryg contains an additional downstroke 'y' which is absent in Actiq, giving the names different shapes and making Omtryg appear longer than Actiq and **Strength:** Single vs. multiple. Omtryg is available in single strength and may be omitted vs. an order for Actiq will require strength as it is available in multiple strengths. There is no numerical overlap or similarity between the strengths. **Frequency:** Omtryg is prescribed as once daily or twice daily vs. Actiq is prescribed as needed for breakthrough pain

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2	**Amdry-D*** (Methscopolamine and Pseudoephedrine) **Dosage Form and Strength:** Oral tablets: 2.5 mg/120 mg **Usual dose:** 1 to 2 tablets daily **Amdry-C*** (Chlorpheniramine, Methscopolamine and Pseudoephedrine) **Dosage Form and Strength:** Oral tablets: 8 mg/2.5 mg/120 mg **Usual dose:** 1 to 2 tablets daily *Product discontinued with generic available	**Orthographic similarity:** The beginning letters 'O' and 'A' and upstroke 't' and 'd' appear orthographically similar when scripted. In addition, both names contain the letters 'm' and letter string 'ry' in similar positions. **Phonetic similarity:** Both names (without the modifier) contain 2 syllables and both syllables, 'Om' / 'Am' and 'dry' / 'tryg' sound phonetically similar when spoken. **Dosage form and route of administration:** Both are available as oral dosage forms **Strength:** Both are available in single strength and may be omitted during prescription writing **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg ends with an additional downstroke 'g' which is absent in Amdry, giving the names different shapes. In addition, Amdry- contains a modifier 'C' or 'D' that needs to be specified for a complete prescription.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3	**Antagon*** (Ganirelix Acetate) **Dosage Form and Strength:** Subcutaneous Solution: 250 mcg/0.5 mL **Usual dose:** 250 mcg subcutaneously once daily during the early- to mid-follicular phase *Product discontinued with generic available	**Orthographic similarity:** The beginning letter strings 'Omtry' and 'Antag' appear orthographically similar when written. **Strength:** Both are available as singles strength and may be omitted during prescription writing. **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg contains an additional downstroke 'g' which is absent in Antagon, giving the names different shapes. In addition, the letter 'g' and 'on' appear orthographically different when scripted. **Dose:** 2 or 4 capsules vs. 250 mcg
4	**Ontak** (Denileukin Diftitox) **Dosage Form and Strength:** Intravenous Solution: 150 mcg/mL **Usual dose:** 9 or 18 mcg/kg/day intravenously over 30 to 60 minutes for 5 consecutive days every 21 days for 8 cycles. Dose based on a 70 kg adult: 630 mcg (4.2 mL) to 1260 mcg (8.4 mL)	**Orthographic similarity:** Both names begin with the letter 'O' and contains an upstroke 't' in similar positions. Additionally, the letter 'm' and 'n' appear orthographically similar when scripted. **Strength:** Both are available as singles strength and may be omitted during prescription writing.	**Orthographic difference:** Omtryg ends with 2 downstrokes 'yg' whereas Ontak ends with an upstroke 'k', giving the names different shapes. **Dose:** 2 or 4 capsules vs. *xx* mcg or mL

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5	**Omontys** (Pegisenatide Acetate) **Dosage Form and Strength:** Injection solution: 10 mg/mL and 20 mg/mL **Usual dose:** 2 to 20 mg intravenously or subcutaneously once monthly **REMS program and voluntary recall on 2/23/13 due to anaphylaxis reaction.	**Orthographic similarity:** Both names begin with the letter string 'Om' and the ending letter strings 'tryg' and 'tys' appear orthographically similar when written	**Orthographic difference:** Omontys contain the letter string 'on' between the letter 'm' and upstroke 't' which is absent is Omtryg, giving the names different shapes. **Route of Administration:** Omtryg is given orally whereas Omontys may be given intravenously or subcutaneously which needs to be specified. **Frequency:** Omtryg is prescribed as once daily or twice daily whereas Omontys is prescribed as once monthly. **Dose:** 2 or 4 capsules vs. *xx* mg

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6	**Entereg** (Alvimopan) **Dosage Form and Strength:** Oral Capsule: 12 mg **Usual dose:** 12 mg by mouth 30 minutes to 5 hours prior to surgery, followed by 12 mg twice daily beginning day after surgery. Max dose and duration = 15 doses (180 mg), 7 days or discharge	**Orthographic similarity:** Both names contain an upstroke 't' in position 3 and end with the downstroke 'g.' In addition, the letters 'm' and 'n' appear orthographically similar when scripted. **Phonetic similarity:** Although Omtryg contains 2 syllables and Entereg contains 3 syllables, Entereg may be spoken in 2 syllables. The first syllable 'Om' and 'En' and last syllable 'tryg' and 'tereg' sound phonetically similar when spoken. **Dosage form and route of administration:** Both are available as oral capsules. **Strength:** Both are available as single strength and may be omitted during prescription writing. **Frequency:** Both may be prescribed as twice daily.	**Orthographic difference:** Omtryg contains an additional downstroke 'y' which is absent in Entereg, giving the names different shapes. In addition, the letter strings 'ere' and 'ry' appear orthographically different when scripted. **Setting of use and requirement:** Entereg is used for short term hospital use only and is part of a REMS program. The REMS require hospital and pharmacy to enroll in EASE (Entereg Access Support and Education) Program.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7	**Ambenyl-D** (Dextromethorphan, Guaifenesin, and Pseudoephedrine) **Dosage Form and Strength:** Oral solution: 15 mg/100 mg/ 3 mg per 5 mL **Usual dose:** 2.5 mL to 10 mL by mouth every 6 hours **Ambenyl Cough*** (Bromodihyphenhydramine and Codeine Phosphate) **Dosage Form and Strength:** Oral solution: 12.5 mg/10 mg per 5 mL **Usual dose:** 5 to 15 mL by mouth every 4 to 6 hours.	**Orthographic similarity:** The beginning letter 'O' / 'A' and the upstroke 't' / 'b' may appear orthographically similar when scripted. In addition, both names contain the letters 'm' and 'y' in similar positions. **Dosage form and route of administration:** Both are available as oral dosage forms. **Strength:** Both are available as single strength which may be omitted during prescription writing.	**Orthographic difference:** Omtryg ends with a downstroke 'g' while Ambenyl ends with an upstroke 'l', giving the names different shapes. In addition, Ambenyl contains the letter string 'en' vs. the letter 'r' in Omtryg between the upstroke and downstroke, making it appear longer when scripted. **Frequency:** Omtryg is prescribed once or twice daily vs. Ambenyl is prescribed every 4 to 6 hours. **Dose:** 2 or 4 capsules vs. *xx* mL or 1 tsp.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8	**Androxy** (Fluoxymesterone) **Dosage Form and Strength:** Oral Tablet: 10 mg **Usual dose:** 2.5 to 20 mg once daily, up to 40 mg daily in divided doses.	**Orthographic similarity:** The beginning letter strings 'Omtr' / 'Andr' and ending letter strings 'yg' / 'xy' appear orthographically similar when scripted. **Dosage form and route of administration:** Both are available as oral dosage forms **Strength:** Both are available in single strengths which may be omitted during prescription writing. **Frequency:** Both may be prescribed as once daily.	**Orthographic difference:** Androxy contains an additional letter 'o' which is absent in Omtryg, making it appear longer when scripted.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
9	**Artane** (Trihexyphenidyl HCl) **Dosage Form and Strength:** Oral Tablet: 2 mg, 5 mg Oral Elixir: 0.4 mg/mL **Usual dose:** 5 to 15 mg once daily	**Orthographic similarity:** The beginning letter strings 'Omt' and 'Art' appear orthographically similar when scripted. **Dosage form and route of administration:** Both are available as oral dosage forms **Frequency:** Both are prescribed once daily	**Orthographic difference:** Omtryg contains 2 downstrokes 'yg' which is absent in Artane giving the names different shapes. In addition, the ending letter strings 'ryg' and 'ane' appear orthographically different when scripted. **Strength:** Single vs. multiple. Omtryg is available in single strength and may be omitted vs. an order for Artane will require strength as it is available in multiple strengths. There is no numerical overlap or similarity between the strengths.
10	**Cometriq** (Cabozantinib) **Dosage Form and Strength:** Oral Capsule: 60 mg, 100 mg, and 140 mg **Usual dose:** 1 capsule by mouth daily	**Orthographic similarity:** The beginning letter strings 'Om' and 'Com' and the ending letter 'g' and 'q' appear orthographically similar when scripted. In addition, both names contain the letter string 'tr' in similar positions. **Dosage form and route of administration:** Both are available as oral capsules **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg contains an additional downstroke 'y' which is absent in Cometriq giving the names different shapes. **Strength:** Single vs. multiple. Omtryg is available in single strength and may be omitted vs. an order for Cometriq will require strength as it is available in multiple strengths. There is no numerical overlap or similarity between the strengths.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
11	**Amitiza** (Lubiprostone) **Dosage Form and Strength:** Oral Capsule: 8 mcg and 24 mcg **Usual dose:** 8 mcg or 24 mcg by mouth twice daily with food and water.	**Orthographic similarity:** The beginning letters 'O' / 'A' and the letters 'y' / 'z' appear orthographically similar when scripted. In addition, both names contain an upstroke 't' in similar positions. **Dosage form and route of administration:** Both are available as oral capsules **Frequency:** Both may be prescribed as twice daily	**Orthographic difference:** Omtryg ends with a downstroke 'g' which is absent in Amitiza giving the names different shapes. **Strength:** Single vs. multiple. Omtryg is available in single strength and may be omitted vs. an order for Amitiza will require strength as it is available in multiple strengths. There is no numerical overlap or similarity between the strengths.
12	**Oravig** (Miconazole) **Dosage Form and Strength:** Buccal Tablet: 50 mg **Usual dose:** Apply 1 tablet to the upper gum region, just above the incisor tooth once daily for 14 days	**Orthographic similarity:** Both names begin with the letter 'O' and end with the letter 'g' **Dosage form and route of administration:** Both are available as oral dosage forms **Strength:** Both are available in singles strengths and may be omitted during prescription writing **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg contains an upstroke 't' and an additional downstroke 'y' which is absent in Oravig, giving the names different shapes.

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13	**Avitene and Avitene Flour** (Microfibrillar Collagen Hemostat) **Dosage Form and Strength:** External Pad and Powder **Usual dose:** Apply directly to the source of bleeding.	**Orthographic similarity:** The beginning letter strings 'Om' and 'Avi' appear orthographically similar when scripted. In addition, both names contain the upstroke 't' in similar positions.	**Orthographic difference:** Omtryg end with 2 downstrokes 'yg' which is absent in Avitene, giving the names different shapes. **Dosage form:** Omtryg is available as a capsule taken orally vs. Avitene is available as an external pad or powder which will need to be specified on the prescription order. **Frequency:** Omtryg is prescribed once or twice daily vs. Avitene is prescribed as needed. **Dose:** 2 or 4 capsules vs. Apply directly or as directed.
14	**Atryn** (Antithrombin III Human Recombinant) **Dosage Form and Strength:** Intravenous solution (reconstituted): 1750 unit **Usual dose:** Dose is individualized based on patients pretreatment functional AT activity level and body weight	**Orthographic similarity:** The beginning letter 'O' and 'A' appear orthographically similar when scripted. In addition, both names contain the letter string 'try' in similar position. **Strength:** Both are available as single strength which may be omitted during prescription writing.	**Orthographic difference:** Omtryg contains an additional letter 'm' between the 2 upstrokes 'O and t' and end with a downstroke 'g' which are absent in Atryn, giving the names different shapes. **Frequency:** Omtryg is prescribed once or twice daily vs. Atryn is prescribed as needed **Dose:** 2 or 4 capsules vs. *xx* units

	Proposed name: ***Omtryg*** (Omega-3-acid ethyl esters) **Dosage form and Strength:** Oral capsules: 900 mg **Usual dose:** 4 capsules daily; may be taken as 4 capsules once daily or 2 capsules twice daily	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
15	**Emtriva** (Emtricitabine) **Dosage Form and Strength:** Oral Capsule: 200 mg Oral solution: 10 mg/mL **Usual dose:** 200 mg capsule once daily or 240 mg (24 mL) solution once daily	**Orthographic similarity:** Both names contain the letter string 'mtr' in similar positions. **Phonetic similarity:** The first syllable 'Om' / 'Em' and second syllable 'tryg' / 'tri' may sound phonetically similar when spoken **Dosage form and route of administration:** Both are available as oral dosage forms **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg ends with 2 consecutive downstrokes 'yg' which is absent in Emtriva, giving the names different shapes. **Phonetic difference:** Emtriva contains a third syllable 'va' which is absent in Omtryg, making it sound longer.
16	**Omnaris** (Ciclesonide) **Dosage Form and Strength:** Nasal Suspension: 50 mcg/Act **Usual dose:** 2 sprays in each nostril once daily	**Orthographic similarity:** Both names begin with the letter string 'Om' **Strength:** Both are available as single strength which may be omitted during prescription writing. **Frequency:** Both may be prescribed as once daily	**Orthographic difference:** Omtryg contains an upstroke 't' in position 3 and ends with 2 consecutive downstrokes 'yg' which are absent in Omnaris, giving the names different shapes. **Dose:** 2 or 4 capsules vs. 2 sprays

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/s/

REASOL AGUSTIN
06/03/2013

LUBNA A MERCHANT
06/03/2013

CAROL A HOLQUIST
06/03/2013