

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205122Orig1s000**

**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: February 14, 2014

Reviewer: Jacqueline Sheppard, PharmD  
Division of Medication Error Prevention and Analysis

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Drug Name and Strengths: Qudexy XR (Topiramate) Extended-release capsules  
25 mg, 50 mg, 100 mg, 150 mg, 200 mg

Application Type/Number: NDA 205122

Applicant/Sponsor: Upsher-Smith Laboratories

OSE RCM #: 2013-16657

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## 1 INTRODUCTION

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

### 1.1 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) evaluated this product under two prior names. (b) (4) was evaluated under OSE RCM # 2013-1235 and was found unacceptable due to (b) (4). (b) (4) was evaluated under OSE RCM # 2013-2248 and was found unacceptable due to (b) (4).

### 1.2 PRODUCT INFORMATION

The following product information is provided in the December 4, 2013 proprietary name submission.

- Active Ingredient: Topiramate
- Indication of Use: Initial monotherapy and/or adjunctive therapy for patients with partial onset seizures or primary generalized tonic-clonic seizures, and adjunctive therapy for patients with seizures associated with Lennox-Gastaut syndrome
- Route of Administration: oral
- Dosage Form: capsules
- Strength: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg
- Dose and Frequency: 25 mg to 400 mg once daily. Dosing may be reduced in patients on concomitant anti-epileptic drugs (AEDs), with renal impairment, and/or undergoing hemodialysis.

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	Initial Dose	Titration	Recommended Dose
<b>Monotherapy (2.1)</b>			
In patients $\geq 10$ years	50 mg once daily	Increase weekly by 50 mg for the first 4 weeks then 100 mg for weeks 5 to 6	400 mg once daily
<b>Adjunctive Therapy (2.1)</b>			
In patients $\geq 17$ with partial onset seizures or LGS	25 to 50 mg once daily	Increase dosage weekly by 25 to 50 mg <sup>a</sup>	200 to 400 mg once daily
In patients $\geq 17$ with primary generalized tonic-clonic seizures	25 to 50 mg once daily	Increase dosage weekly by 25 to 50 mg	400 mg once daily
In patients $\geq 2$ with partial onset seizures, primary generalized tonic-clonic seizures or LGS	25 mg (b) (4) based on a range of 1 to 3 mg/kg /day) nightly for the first week	Increase dosage at 1- or 2-week intervals by 1 to 3 mg/kg once daily	5 to 9 mg/kg once daily

- How Supplied: 30, 90, and 500 count bottles for retail; (b) (4)
- Storage: Controlled room temperature
- Container and Closure Systems: High-density polyethylene (HDPE) container (b) (4)

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products 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***

There is no USAN stem present in the proposed proprietary name.<sup>1</sup>

### ***2.2.2 Components of the Proposed Proprietary Name***

The proposed proprietary names contains two components 1) the proposed root name, Qudexy, and 2) a modifier, XR. See section 2.2.6 for our evaluation of the proposed modifier.

### ***2.2.3 FDA Name Simulation Studies***

Sixty 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. Significant trends include the misinterpretation of the "Qu" in Qudexy for "Chew," "Chu," "Cu," or "Shu" and the final "y" as an "i" sounds in the verbal studies. A majority of the written studies were interpreted correctly. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

### ***2.2.4 Failure Mode and Effects Analysis of Similar Names***

The potential letter and letter string variations listed in Appendix B were used to search for names with possible orthographic and phonetic similarity to the proposed proprietary name, Qudexy XR (see Table 1). Our analysis of the thirty-seven names contained in Table 1 determined all thirty-seven names will not pose a risk for confusion as described in Appendices D through E.

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<sup>1</sup> USAN stem list searched December 26, 2013.

<b>Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)</b>					
<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Qnexa <sup>***</sup>	FDA	Ozurdex	FDA	Ocudex	FDA
Quintex	FDA	Q-Dryl	FDA		
<b>Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Codeprex	FDA				
<b>Look and Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Acutect	Ext	Bumex	Ext	Candex	Ext
Capex	Ext	Casodex	Ext	Cedax	Ext
Totect	Ext	Trymex	Ext	Chenix	Ext
Chymex	Ext	Clobex	Ext	Codoxy	Ext/FDA
Codrix	Ext	Cognex	Ext	Copegus	Ext
Cormax	Ext	Didrex	Ext	Doxy 100	Ext
Doxy 200	Ext	Efudex	Ext	Kionex	Ext
Lidex – E	Ext	Quide	Ext	Quinact	Ext
Quinidex	Ext/FDA	Quixin	Ext	Qutenza	Ext
Staxyn	Ext	Tenex	Ext	Tetrex	Ext
Tobrex	Ext				

### **2.2.5 Communication of DMEPA’s Analysis at Midpoint of Review**

DMEPA communicated our findings to the Division of Neurology Products via e-mail on January 17, 2014. At that time we also requested additional information or concerns that

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could inform our review. Per e-mail correspondence from the Division of Neurology Products on January 24, 2014, they stated no additional concerns with the proposed proprietary name, Qudexy XR.

### **2.2.6 FMEA of Modifier**

The Applicant selected the modifier “XR” to convey the extended-release properties of this product and help distinguish it from the currently marketed immediate-release topiramate products.

The proposed frequency of administration of this product is once daily. Without a modifier, the frequency of administration alone may not convey that this product is an extended release product. Immediate release topiramate products are usually prescribed twice a day but may also be prescribed once daily. The lack of a modifier along with practitioner’s familiarity with the immediate release topiramate products may lead practitioners to erroneously believe that the proposed product is also immediate release rather than extended release. Furthermore, post-marketing medication errors have identified cases of chewing, splitting, and crushing of extended-release products. In some cases, the reporters indicate they were unaware the product was extended release. Although we note Qudexy XR capsules can be swallowed whole or administered by sprinkling the capsule contents on a small amount of soft food, the contents should not be chewed. While we recognize there is no single, standard modifier currently on the market today that can denote the specific manipulation instructions for this product, including a modifier may signal to healthcare practitioners that this product differs from the currently marketed immediate-release topiramate formulations on the market.

The modifier “XR” has been used to communicate once or twice daily administration, and the modifier “XR” has not been cited as a source of post-marketing confusion. Therefore, the use of the modifier “XR”, in this circumstance, is consistent with other XR products that are currently marketed. Furthermore, the modifier “XR” is consistent with Trokendi XR, another currently marketed extended-release topiramate product that is also administered once daily.

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

## **3 CONCLUSIONS**

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

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

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your December 4, 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](http://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. *Natural Medicines Comprehensive Databases* ([www.naturaldatabase.com](http://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.

**10. *Access Medicine* ([www.accessmedicine.com](http://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.

**11. *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.

**12. *Red Book* ([www.thomsonhc.com/home/dispatch](http://www.thomsonhc.com/home/dispatch))**

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

**13. *Lexi-Comp* ([www.lexi.com](http://www.lexi.com))**

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

**14. *Medical Abbreviations* ([www.medilexicon.com](http://www.medilexicon.com))**

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

**15. *CVS/Pharmacy* ([www.CVS.com](http://www.CVS.com))**

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

**16. *Walgreens* ([www.walgreens.com](http://www.walgreens.com))**

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

**17. *Rx List* ([www.rxlist.com](http://www.rxlist.com))**

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

**18. Dogpile ([www.dogpile.com](http://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.

**19. 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.<sup>2</sup>

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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<sup>2</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.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.<sup>3</sup>

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).

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<sup>3</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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

<b>Type of Similarity</b>	<b>Considerations when Searching the Databases</b>		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	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	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
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	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

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

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

### **1. Database and Information Sources**

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

### **2. Expert Panel Discussion**

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

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

### **3. FDA Prescription Simulation Studies**

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

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

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

#### **4. Comments from Other Review Disciplines**

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

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

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

#### **5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> 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

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<sup>4</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess 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, Qudexy XR	Scripted May Appear as	Spoken May Be Interpreted as
Q	O, C, G, A, L	K, Que, Cu
q	g, j, z, p, a	k
u	n, y, v, w, a, e, i, o	Y, any vowel
d	cl, ci, ol	B, t
e	a, i, l, o, u	Any vowel
x	a, d, f, k, n, p, r, t, v, y, s	Ks, kz, s, z
y	f, p, u, v, x, z, j	e, i
X	d, f, K, P, t, U, V, Y	KS, KZ, S, Z
R	B, Pr, K	WR
Letter Strings		
Qu		Chew, Shu

**Appendix C:** Prescription Simulation Samples and Results

**Figure 1. Qudexy XR Study (Conducted on December 2, 2013)**

<b>Handwritten Requisition Medication Order</b>	<b>Verbal Prescription</b>
<p data-bbox="186 703 406 735"><u>Medication Order:</u></p> <p data-bbox="203 745 917 819"><i>Qudexy XR 100mg once daily</i></p> <hr/> <p data-bbox="186 861 470 892"><u>Outpatient Prescription:</u></p> <p data-bbox="235 924 917 1228"><i>Qudexy XR 200mg 1 cap po once daily #30</i></p> <hr/>	<p data-bbox="950 703 1193 735">Qudexy XR 200 mg</p> <p data-bbox="950 745 1193 777">One by mouth daily</p> <p data-bbox="950 798 998 829">#30</p>

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

192 People Received Study  
60 People Responded

Study Name: Qudexy XR

<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>
ANDEXY XR (1)	CHEWDEXI XR (2)	QADEXY XR (7)
QUDEREY XR (1)	CHEWDEXY XR (1)	QUADEXY XR (1)
QUDESEY XR (1)	CHUDEXI XR (2)	QUDEXY XR (10)
QUDESXY XR (1)	CUDEXI XR (3)	QUDEXY XR (1)
QUDEXY (1)	CUEDEXI XR (1)	QUOLEXY XR (1)
QUDEXY XR (1)	QDEXI XR (1)	
QUDEXY XR (17)	QDEXY XR (1)	
	QUDEXI XR (3)	
	QUDEXY XR (1)	
	QUEDEXY XR (1)	
	SHUDEXI XR (1)	

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

No.	Proprietary Name	Active Ingredient	Similarity to Qudexy XR	Failure preventions
1.	Acutect	Technetium TC-99M Apcitide	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
2.	Bumex	Bumetanide	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
3.	Candex	Nystatin	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
4.	Capex	Fluocinolone	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
5.	Casodex	Bicalutamide	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
6.	Cedax	Ceftibuten dihydrate	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
7.	Chenix	Chenodiol	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
8.	Chymex	Bentiromide	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
9.	Codeprex	Chlorpheniramine polistirex; codeine polistirex	Sound Alike	The pair has sufficient phonetic differences.
10.	Cognex	Tacrine hydrochloride	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
11.	Copegus	Ribavirin	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
12.	Cormax	Clobetasol propionate	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
13.	Didrex	Benzphetamine hydrochloride	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
14.	Doxy 100	Doxycycline	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
15.	Doxy 200	Doxycycline	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
16.	Efudex	fluorouracil	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
17.	Kionex	Sodium polystyrene sulfonate	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.

No.	Proprietary Name	Active Ingredient	Similarity to Qudexy XR	Failure preventions
18.	Qnexa <sup>***</sup>	Phentermine and Topiramate	Look Alike	NDA 022580 - The name was found unacceptable under OSE review 2012-187. The product was approved under the proprietary name Qsymia.
19.	Quide	Piperacetazine	Look and Sound Alike	The product is a sedative used in veterinary medicine.
20.	Quinact	Quinidine gluconate	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
21.	Quinidex	Quinidine sulfate	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
22.	Quixin	levofloxacin	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
23.	Qutenza	Capsaicin	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
24.	Staxyn	vardeafil	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
25.	Tenex	guanfacine	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
26.	Tetrex	Tetracycline Phosphate Complex	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
27.	Tobrex	tobramycin	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
28.	Totect	Dexrazoxane	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.
29.	Trymex	Triamcinolone Acetonide	Look and Sound Alike	The pair has sufficient phonetic and orthographic differences.

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

**Appendix E:** Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p><i>Qudexy XR (Topiramate XR)</i></p> <p><b>Dosage Form:</b> extended release capsule</p> <p><b>Strengths:</b> 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</p> <p><b>Usual Dose:</b> 25 mg/day to 400 mg/day</p>	<p><b>Failure Mode:</b> Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	<p><i>Clobex (Clobetasol propionate)</i></p> <p><u>Dosage Forms:</u> Lotion, Shampoo, Spray</p> <p><u>Strength:</u> 0.05%</p> <p><u>Usual Dose:</u></p> <p><i>Lotion:</i> Apply to affected area twice daily; do not use for longer than 2 weeks</p> <p><i>Shampoo:</i> Apply to affected area once daily; do not use longer than 4 weeks</p> <p><i>Spray:</i> Apply to affected area twice daily; Do not use longer than 4 weeks</p>	<p><u>Orthographic:</u></p> <p>The letter strings “obex” and “udex” can look similar when scripted. The letter pair “Cl” can look like the letter “Q” when scripted.</p> <p><u>Frequency of administration:</u></p> <p>Both products can be prescribed once daily.</p>	<p><u>Orthographic:</u></p> <p>The down stroke “y” at the end of Qudexy gives length and orthographic differentiation compared to Clobex. Additionally, if the modifier XR in Qudexy XR is not dropped, it gives further differentiation.</p> <p><u>Strength:</u></p> <p>Clobex is a single strength product; therefore, strength may be omitted on the prescription. Qudexy XR is available in multiple strengths, so strength must be included on the prescription. There is no overlap in strengths between the two products.</p> <p><u>Dosage:</u></p> <p>The dosage is different between the two products. Prescriptions would be written as apply small amount of Clobex or use as directed vs. a specific mg dosage or number of capsules of Qudexy XR.</p> <p><u>Dosage Form:</u></p> <p>Clobex is available in multiple dosage forms, so dosage form must be included on the prescription, while Qudexy is only available in capsule form. There is no overlap in dosage forms between the two products.</p>

No.	<p><b><i>Qudexy XR (Topiramate XR)</i></b></p> <p><b>Dosage Form: extended release capsule</b></p> <p><b>Strengths: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</b></p> <p><b>Usual Dose:</b></p> <p><b>25 mg/day to 400 mg/day</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
2.	<p><i>Codoxy (Aspirin, Oxycodone Hydrochloride, Oxycodone terephthalate)</i></p> <p><b>Dosage Form:</b> Tablet</p> <p><b>Strength:</b> 325 mg/ 4.5 mg/ 0.38 mg</p> <p><b>Usual Dose:</b></p> <p>One tablet every 6 hours as needed for pain</p>	<p><u>Orthographic:</u></p> <p>The upper case “Q” can look like a “C” when scripted. The letters “a,” “o,” and “e” look similar when scripted. Both names have a third position upstroke “d” and end in the suffix “xy.” Both root names contain six letters in the same word shape. The XR modifier in Qudexy may be dropped because there is not an immediate release Qudexy product.</p> <p><u>Phonetic:</u></p> <p>Both words contain three syllables. The ending infix and suffix “doxy” vs. “dexy” sound very similar. A “Q” can be misinterpreted as a “C” sound.</p> <p><u>Dose and Route of administration:</u></p> <p>Both medications are oral products and can be prescribed as take one tablet/capsule.</p>	<p><u>Strength:</u></p> <p>Codoxy is a single strength product; therefore, strength may be omitted on the prescription. Qudexy XR is available in multiple strengths, so strength must be included on the prescription.</p> <p><u>Dosage:</u></p> <p>Although there is numerical overlap between the aspirin component of Codoxy and Qudexy XR (Codoxy 325 mg and Qudexy XR 325 mg), it is unlikely that only the aspirin component would be written in this multi-ingredient product.</p> <p><u>Frequency of Administration:</u></p> <p>Codoxy is dosed four times daily as needed for pain while Qudexy XR is dosed one time daily.</p>

No.	<p><b><i>Qudexy XR (Topiramate XR)</i></b></p> <p><b>Dosage Form:</b> extended release capsule</p> <p><b>Strengths:</b> 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</p> <p><b>Usual Dose:</b> 25 mg/day to 400 mg/day</p>	<p><b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
3.	<p><i>Codrix (Acetaminophen/Codeine Phosphate)</i></p> <p><b>Dosage Form:</b> Tablet</p> <p><b>Strength:</b> 500 mg / 60 mg 500 mg / 30 mg 500 mg / 15 mg</p> <p><b>Usual Dose:</b> <i>Adults:</i> Acetaminophen (300 mg – 1000 mg)/ Codeine (15 mg – 60 mg) every 4 hours as needed for pain <i>Pediatrics:</i> 0.5 mg/kg (codeine component) every 4 hours as needed for pain</p>	<p><b>Orthographic:</b> The letter pair “Co” can look like “Qu” when scripted. Both names have a third position upstroke “d.” The letter pairs “ex” and “ix” look similar when scripted.</p> <p><b>Dose and Route of administration:</b> Both medications are oral products and can be prescribed as take one tablet/capsule.</p> <p><b>Strength:</b> Since Codrix is available in multiple strengths with the same Acetaminophen component in all strengths, there is potential that only the Codeine component of Codrix is written on a prescription. There is numerical similarity between Codrix 15 mg (Codeine component) and Qudexy XR 150 mg.</p>	<p><b>Orthographic:</b> The down stroke “y” at the end of Qudexy gives length and orthographic differentiation compared to Codrix. Additionally, if the modifier XR in Qudexy XR is not dropped, it gives further differentiation.</p> <p><b>Frequency of Administration:</b> Codrix is dosed six times daily as needed for pain while Qudexy XR is dosed one time daily.</p>

No.	<p><b><i>Qudexy XR (Topiramate XR)</i></b></p> <p><b>Dosage Form: extended release capsule</b></p> <p><b>Strengths: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</b></p> <p><b>Usual Dose: 25 mg/day to 400 mg/day</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
4.	<p><i>Lidex – E (Fluocinonide)</i></p> <p><u>Dosage Form:</u> Topical Cream</p> <p><u>Strength:</u> 0.05%</p> <p><u>Usual Dose:</u> Apply to affected area two to four times daily</p>	<p><u>Orthographic:</u></p> <p>An upper case “L” can look like an upper case “Q” when scripted. Both names contain the letter strings “dex” in the third position.</p>	<p><u>Orthographic:</u></p> <p>The down stroke “y” at the end of Qudexy gives orthographic differentiation. Additionally, if not dropped, the modifiers E in Lidex-E and XR in Qudexy XR give additional orthographic differentiation.</p> <p><u>Strength and dosage:</u></p> <p>Lidex-E is a single strength product; therefore, strength may be omitted on the prescription. Qudexy XR is available in multiple strengths, so strength must be included on the prescription. The products do not share overlapping strengths or doses.</p>
5.	<p><i>Ocu-dex (Dexamethasone Sodium Phosphate)</i></p> <p><u>Dosage Forms and Strength:</u></p> <p><i>Ointment, 0.05%</i></p> <p><i>Solution, 0.01%</i></p> <p><u>Usual Dose:</u></p> <p><i>Solution</i> – Instill one or two drops into the conjunctival sac every hour during the day and every two hours during the night. When a favorable response is observed, reduce dosage to one drop every four hours. Further reduce dose to one drop three to four times daily for symptom control.</p> <p><i>Ointment</i> – Apply one to four times daily.</p>	<p><u>Orthographic:</u></p> <p>An upper case “O” can look like an upper case “Q” when scripted. Both names contain the letter strings “dex.”</p> <p><u>Frequency of administration:</u></p> <p>Both products can be prescribed once daily.</p>	<p><u>Orthographic:</u></p> <p>The down stroke “y” at the end Qudexy gives orthographic differentiation. Additionally, if not dropped, the modifier XR in Qudexy XR gives additional orthographic differentiation.</p> <p><u>Dosage form:</u></p> <p>Ocu-dex is available as either an ointment or a solution. While dosage forms needs to be indicated for Ocu-dex, the dosage form for Qudexy XR may be omitted, since it is only available in one dosage form. The dosage forms of the two products do not overlap,</p> <p><u>Strength and dosage:</u></p> <p>Ocu-dex is a single strength product; therefore, strength may be omitted on the prescription. Qudexy XR is available in multiple strengths, so strength must be included on the prescription. The products do not share overlapping strengths or doses.</p>

No.	<p><i>Qudexy XR (Topiramate XR)</i></p> <p><b>Dosage Form:</b> extended release capsule</p> <p><b>Strengths:</b> 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</p> <p><b>Usual Dose:</b> 25 mg/day to 400 mg/day</p>	<p><b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
6.	<p><i>Ozurdex (Dexamethasone intravitreal implant)</i></p> <p><u>Dosage Form:</u> Intravitreal Implant</p> <p><u>Strength:</u> 0.7 mg</p> <p><u>Usual Dose:</u> One implant</p>	<p><u>Orthographic:</u></p> <p>An upper case “O” can look like an upper case “Q” when scripted. Both names contain the letter strings “dex.”</p>	<p><u>Orthographic:</u></p> <p>The letter strings “zur” in the infix of Ozurdex adds length to the infix compared to Qudexy, and the down stroke “y” at the end of Qudexy gives orthographic differentiation. Additionally, if not dropped, the modifier XR in Qudexy XR gives additional orthographic differentiation.</p> <p><u>Strength:</u></p> <p>Ozurdex is a single strength product; therefore, strength may be omitted on the prescription. Qudexy XR is available in multiple strengths, so strength must be included on the prescription. The products do not share overlapping strengths.</p> <p><u>Setting of Use:</u></p> <p>Ozurdex is an intravitreal device and must be implanted under controlled aseptic conditions. Qudexy XR is an oral tablet that does not require administration under controlled aseptic conditions.</p>

No.	<p><b><i>Qudexy XR (Topiramate XR)</i></b></p> <p><b>Dosage Form: extended release capsule</b></p> <p><b>Strengths: 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</b></p> <p><b>Usual Dose: 25 mg/day to 400 mg/day</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
7.	<p><i>Q-dryl (diphenhydramine hydrochloride)</i></p> <p><u>Dosage Form:</u> Oral solution</p> <p><u>Strength:</u> 12.5 mg/ 5 ml</p> <p><u>Usual Dose:</u></p> <p><i>Children 6 years to under 12 years:</i> 5 ml to 10 ml every 4 to 6 hours; no more than 60 ml in 24 hours</p> <p><i>Adults and children 12 and older:</i> 10 ml to 20 ml every 4 to 6 hours; no more than 120 ml in 24 hours</p>	<p><u>Orthographic:</u></p> <p>Both names begin with the letter “Q” and contain an upstroke “d” in similar positions.</p> <p><u>Dosage:</u></p> <p>There is numerical similarity in dosage between Q-dryl 5 mL, 10 mL, 15 mL, and 20 mL and Qudexy XR 50 mg, 100 mg, 150 mg, and 200 mg.</p> <p><u>Route of administration:</u></p> <p>Both medications are oral products.</p>	<p><u>Orthographic:</u></p> <p>The letter strings “ryl” in Q-dryl look different from “exy” in Qudexy when scripted. Additionally, if not dropped, the modifier XR in Qudexy XR gives additional orthographic differentiation.</p> <p><u>Frequency of Administration:</u></p> <p>Q-dryl is dosed four to six times daily as needed while Qudexy XR is dosed one time daily.</p>

No.	<p><i>Qudexy XR (Topiramate XR)</i></p> <p><b>Dosage Form:</b> extended release capsule</p> <p><b>Strengths:</b> 25 mg, 50 mg, 100 mg, 150 mg, 200 mg</p> <p><b>Usual Dose:</b> 25 mg/day to 400 mg/day</p>	<p><b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
8.	<p><i>Quintex (Phenylephrine/Guaifenesin)</i></p> <p><u>Dosage Form:</u> Syrup</p> <p><u>Strength:</u> 100 mg/7.5 mg/ 5ml</p> <p><u>Usual Dose:</u> 2.5 to 10 ml every 4 to 6 hours</p>	<p><u>Orthographic:</u></p> <p>Both names begin with the letter “Q.” The letter strings “tex” look like “dex” when scripted.</p> <p><u>Dosage:</u></p> <p>There is numerical similarity in dosage Quintex 2.5 mL, 5 mL, and 10 mL and Qudexy XR 25 mg, 50 mg, and 100 mg.</p> <p><u>Route of Administration:</u></p> <p>Both are oral products.</p>	<p><u>Orthographic:</u></p> <p>The letters string “uin” lengthens the prefix of Quintex and gives sufficient orthographic differentiation. Additionally, if not dropped, the modifier XR in Qudexy XR gives additional orthographic differentiation.</p> <p><u>Frequency of Administration:</u></p> <p>Quintex is dosed four to six times daily while Qudexy XR is dosed one time daily.</p>

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JACQUELINE E SHEPPARD  
02/14/2014

JULIE V NESHIEWAT  
02/14/2014

IRENE Z CHAN  
02/18/2014