

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**202292Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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

**Proprietary Name Review--Final**

Date	November 2, 2012
Reviewer	Denise V. Baugh, PharmD, BCPS Division of Medication Error Prevention and Analysis
Team Leader	Lubna Merchant, PharmD, M.S. Division of Medication Error Prevention and Analysis
Drug Name	Fulyzaq (Crofelemer) Delayed Release Tablets
Strength:	125 mg
Application Type/Number	NDA 202292
Applicant	Salix Pharmaceuticals, Inc.
OSE RCM	2012-2500

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

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## 1 INTRODUCTION

This re-assessment of the proposed proprietary name, Fulyzaq is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, *Fulyzaq*, acceptable in OSE Review 2012-1779 dated September 5, 2012.

## 2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review # 2012-1779.

We note that although none of the proposed product characteristics were altered, CMC has determined that this is a delayed release product. Therefore, we considered whether or not the name Fulyzaq needed a modifier to emphasize the delayed-release nature of the product. Based upon our post marketing experience, the absence of a modifier may lead to wrong technique errors or wrong frequency of administration errors. Wrong technique errors are associated with confusion between the different release formulations of the same drug product. This confusion has resulted in chewing, splitting, or crushing the extended-release oral dosage forms (by patients or healthcare practitioners) when these products were intended to be administered intact or capsules opened and mixed with certain foods or liquids. Wrong frequency errors have involved the administration of the delayed-release dosage form at intervals more frequent than labeled, (e.g. taking a twice daily drug four times a day).

With respect to wrong technique errors, we do not believe Fulyzaq poses the same risk for wrong technique errors as identified above because there is no immediate release formulation of this product available on the market. Therefore, there is no expectation or bias associated with manipulating it prior to administration. Additionally, we reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms That Should Not Be Crushed" to identify if a modifier exists that could possibly convey that a delayed-release dosage form can be manipulated (note, the list refers to delayed-release as "slow-release"). We conclude that there is no standard single modifier currently on the market today that speaks to whether a delayed-release product can or cannot be manipulated prior to administration. As such, the appropriate handling of this drug product (e.g, swallow whole) may be managed in the label and labeling.

With respect to the potential for wrong frequency of administration errors, we do not anticipate that Fulyzaq is prone to be administered at the wrong frequency of administration. As stated above, there is no immediate release formulation of this drug that is administered more often than twice daily. In addition, adding a modifier to communicate the delayed-release nature of the product, may cause further confusion by wrongly insinuating that administration is once daily, as some currently marketed delayed-release formulations recommend. Therefore, we find that the risk of Fulyzaq being administered at the wrong frequency is minimal, irrespective of the inclusion of a modifier in the proprietary name.

Given the totality of the factors considered above, there is no compelling evidence to support the necessity to request a modifier for the proposed proprietary name, Fulyzaq, at this time.

We also evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded five new names ( (b) (4) (b) (4) (b) (4) Pristiq, and (b) (4) thought to look or sound similar to Fulyzaq and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Fulyzaq and lead to medication errors. This analysis determined that the name similarity between Fulyzaq and the identified names was unlikely to result in medication error for the reasons presented in Appendices A and B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 25, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on November 1, 2012 and did not have concerns regarding the proposed name from a promotional perspective.

### **3 CONCLUSIONS**

The re-evaluation of the proposed proprietary name, Fulyzaq, did not identify any vulnerability that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Fulyzaq, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Office of Gastroenterology and Inborn Errors Products (DGIEP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Franklin Stephenson, OSE Project Manager, at 301-796-3872.

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## 4 REFERENCES

### 1. OSE Reviews

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

Proprietary Name	Active Ingredient	Similarity to (b) (4)	Failure Preventions
(b) (4)	(b) (4)	Sound Alike	(b) (4)
(b) (4)	(b) (4)	Look Alike	(b) (4)

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**Appendix B:** 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.	<b>Proposed Name:</b> <b>Fulyzaq</b> <b>Dosage Form: Tablet</b> <b>Strength: 125 mg</b> <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b> <b>Causes (could be multiple)</b>	<b>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</b>
1.	(b) (4)		
2.	Pristiq (Desvelafaxine) Extended-release Tablet 50 mg, 100 mg <u>Usual dose:</u> 50 mg orally once daily with or without food	Orthographic similarity stems from the similar appearance of their first letters ('P' vs. 'F') in some handwriting samples and the fact that they share the same last letter ('q').	The proposed proprietary name, Fulyzaq includes one down stroke ('y') and the marketed name, Pristiq includes a cross stroke ('t') giving these names different shapes.  Differing product characteristics include the dose (one tablet or 125 mg vs. 50 mg or 100 mg).  The marketed proprietary name, Pristiq is available in two different strengths and therefore this information is needed to dispense/administer the medication as intended. The strengths do not overlap numerically and are not achievable.

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No.	<b>Proposed Name:</b> <b>Fulyzaq</b> <b>Dosage Form: Tablet</b> <b>Strength: 125 mg</b> <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b> <b>Causes (could be multiple)</b>	<b>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</b>
3.	<div style="text-align: right;">(b) (4)</div>		

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/s/  
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DENISE V BAUGH  
11/05/2012

LUBNA A MERCHANT  
11/05/2012

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

**Proprietary Name Review**

Date: September 5, 2012

Reviewer: Anne Crandall Tobenkin, PharmD  
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, PharmD, M.S.  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name(s): Fulyzaq (Crofelemer) Tablets

Strength: 125 mg

Application Type/Number: NDA 202292

Applicant/Sponsor: Salix Pharmaceuticals, Inc.

OSE RCM #: 2012-1779

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## 1 INTRODUCTION

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

### 1.1 REGULATORY HISTORY

This NDA has undergone multiple proprietary name reviews including; (b) (4) (OSE review # 2011-4643) which was found unacceptable by DMEPA, (b) (4)\*\*\* (OSE review not completed, DMEPA tele-con with Applicant) which was found unacceptable (b) (4), and (b) (4) (OSE review not completed, DMEPA tele-con with Applicant) which was also found unacceptable. Due to the impending PDUFA date of September 5, 2012, the Applicant was encouraged to submit multiple proprietary names for the product.

Subsequently, the Applicant submitted three names on August 1, 2012: (b) (4) Fulyzaq, and (b) (4)\*\*\*. Upon review, the name (b) (4) was found unacceptable due to orthographic similarity with (b) (4). The Applicant was notified via tele-con with DMEPA on August 23, 2012. The Applicant withdrew the name (b) (4) on August 27, 2012 and submitted Fulyzaq as the primary name for NDA 202292.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the August 27, 2012 proprietary name submission.

- Active Ingredient: Crofelemer
- Indication of Use: Control and symptomatic relief of diarrhea in patients with HIVS/AIDS on anti-retroviral therapy
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 125 mg (single strength)
- Dose and Frequency: 125 mg twice daily
- How Supplied: 60 count bottle
- Storage: Room temperature
- Container and Closure Systems: (b) (4)

## 2. RESULTS

The following sections provide the information obtained and considered in the 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

Gastroenterology and Inborn Error Products (DGIEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

## **2.2 SAFETY ASSESSMENT**

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

### ***2.2.1 United States Adopted Names (USAN) SEARCH***

The August 13, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

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

The Applicant indicated in their submission that the proposed name, Fulyzaq, is not a derivation of another name and has no intended meaning. This proprietary name is comprised of a single word, Fulyzaq, and does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

### ***2.2.4 FDA Name Simulation Studies***

Fifty practitioners participated in DMEPA's prescription studies. Twenty three participants (about 50%) interpreted the name correctly as Fulyzaq. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Significant trends in the written simulation studies include: "g" for "q", and "J", "T", and "Z" for "F". Significant trends in the oral simulation study include: "o" for "u" and "y" and "i" for "y". See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### ***2.2.5 Comments from Other Review Disciplines***

In response to the OSE, August 9, 2012 e-mail, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

### ***2.2.6 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, Fulyzaq. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Fulyzaq identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

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

Look Similar		Sound Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	EPD	Ferrelecit	EPD	(b) (4)	EPD
(b) (4)	EPD	Flomax	EPD	(b) (4)	EPD
Prevpac	EPD	Fluotrex	EPD		
Fabrazyme	EPD	Folicet	EPD		
(b) (4)	EPD				
Fulvicin	EPD				
Jalyn	EPD				
Folotyn	EPD				
Pertzye	EPD				
Zolyse	EPD				
Furamag	EPD				

Our analysis of the seventeen names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 12 names will not pose a risk for confusion as described in Appendix D through E.

**2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines**

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Error Products (DGIEP) via e-mail on August 23, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence with DGIEP, no additional concerns were conveyed regarding the proposed proprietary name, Fulyzaq.

**2 CONCLUSIONS**

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

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

## **2.1 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Fulyzaq, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your August 27, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

### 3 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. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://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](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.

**11. 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.

**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](http://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](http://www.lexi.com))**

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

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

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

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

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

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

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

**18. 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.

**19. 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.

**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.<sup>1</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

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>2</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>2</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>3</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>3</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

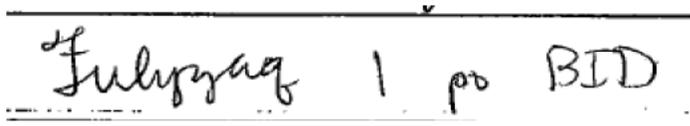
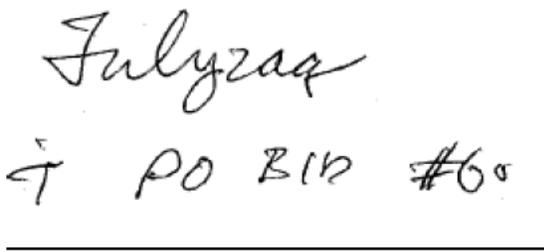
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name: Fulyzaq	Scripted May Appear as:	Spoken May Be Interpreted as:
F	T, J	“B”
u	a, o, e, ir	
l	t, f, h, b	
y	g, j, v, z	“i”, “ee”
z	g, j, y	“s”, “c”
a	u, e, o,	
q	a, g, y	“k”, “ck”, “x”

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

**Figure 1. Prescription Simulation Study (Conducted on August 21, 2012)**

Handwritten Inpatient and Outpatient Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p>  <p><u>Outpatient Prescription:</u></p> 	<p>Fulyzaq 1 po bid</p>

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

189 People Received Study

50 People Responded

Study Name: Fulyzaq

	Total	14	19	17
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
FALYZAQ	0	0	1	1
FALZQAQ	0	0	1	1
FOLAZAC	0	1	0	1
FOLAZACK	0	1	0	1
FOLEZAC	0	1	0	1
FOLISAC	0	1	0	1
FOLIZAC	0	10	0	10
FOLIZACK	0	1	0	1
FOLOZAC	0	2	0	2
FULIZAC	0	1	0	1
FULOZAC	0	1	0	1
FULYZAG	2	0	0	2
FULYZAQ	12	0	11	23
JULYZAQ	0	0	1	1
TULYZAQ	0	0	2	2
ZULYZAQ	0	0	1	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Fulyzaq	Failure preventions
1.	(b) (4)	Crofelemer	Orthographic	Alternate name for product being evaluated in this review
2.	(b) (4)	(b) (4)	Phonetic and orthographic	(b) (4)
3.	(b) (4)	(b) (4)	Orthographic	(b) (4)
4.	Ferrelecit	Sodium Ferric Gluconate	Phonetic	Name is phonetically distinct from Fulyzaq and not likely to result in confusion

**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.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
1.	(b) (4)		
2.	<b>Prevpac</b> (Amoxicillin, Clarithromycin, Lansoprazole)  - 500 mg, 500 mg, 30 mg capsules in a 14 day pack  - 1000 mg, 500 mg, 30 mg by mouth twice daily	<b>Orthographic similarities</b> - “F” and “P” appear similar when scripted - Both names have a downstroke in the middle of the name  <b>Product characteristic overlaps</b> - Route of administration (oral) - Frequency of administration (twice daily)	<b>Orthographic differences</b> - Fulyzaq has at least two downstrokes (three if “z” is scripted) vs. Prevpac has one downstroke giving the name a different shape when scripted - Fulyzaq has an upstroke in the middle of the name vs. Prevpac does not have an upstroke in the middle of the name giving the name a different shape when scripted  <b>Product characteristic differences</b> - Dose (one capsule vs. multiple capsules)

No.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
3.	<b>Fabrazyme</b> (Agalsidase Beta)  - 5 mg, 35 mg powder for injection  - 1 mg/kg infusion every 2 weeks	<b>Orthographic similarities</b> - Both names begin with "F" - Both names have an upstroke in the middle of the name - Both names have a downstroke in the middle of the name  <b>Product characteristic overlaps</b> - none	<b>Orthographic differences</b> - Fulyzaq has seven letters vs. Fabrazyme has nine letters making the name appear longer when scripted - Fulyzaq has one letter in between the upstroke and the downstroke vs. Fabrazyme has three letters in between the middle upstroke and downstroke giving the name a different shape - Fulyzaq ends with an upstroke vs. Fabrazyme has two letters that follow the final upstroke giving the name a different shape  <b>Product characteristic differences</b> - Frequency of administration (twice daily vs. once every two weeks) - Dose (1 tablet or 125 mg vs. weight based regimen mg/kg)
4.	<div style="text-align: right;">(b) (4)</div>		

No.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
5.	<b>Flomax</b> (Tamsulosin) - 0.4 mg oral capsule - 0.4 mg to 0.8 mg by mouth once daily	<b>Phonetic similarities</b> - Both names begin with the sound “F” - Both names have a similar ending, “ax” vs. “aq”  <b>Product characteristic overlaps</b> - Strength (both single strength) - Route of administration (oral) - Dosage form (oral solid)	<b>Phonetic differences</b> - Fulyzaq has three syllables vs. Flomax has two syllables - The first syllable of Fulyzaq ends with the sound “l” vs. Flomax ends with the sound “oh”  <b>Product characteristic differences</b> - Frequency of administration (once daily vs. twice daily)
6.	<b>Fluotrex</b> (Fluocinolone) - Discontinued, generic available - 0.025% topical cream and ointment, 0.01% topical solution and cream - Apply to affected area two to four times daily	<b>Phonetic similarities</b> - Both names begin with the sound “F” - Both names consist of three syllables - Both names end with a similar sound “aq” vs. “ex”  <b>Product characteristic overlaps</b> - Frequency of administration (twice daily)	<b>Phonetic differences</b> - The first syllable of Fulyzaq ends with the sound “l” vs. Fluotrex ends with the sound “oo” - The middle syllable of Fulyzaq has the sound “ee” vs. Fluotrex has the sound “oh”  <b>Product characteristic differences</b> - Strength (125 mg, single strength, not required on prescription vs. 0.025%, 0.01%, although some similar numbers, the presence of leading zeros and percent sign will help differentiate the strengths) - Dosage form (tablet vs. cream, ointment, solution)
7.	<b>Fulvicin P/G, U/F</b> (Griseofulvin) - Fulvicin off market, generic available - U/F: 250 mg, 500 mg oral tablet - P/G: 125 mg, 165 mg, 250 mg, 330 mg - 125 mg to 1 g by mouth per day in single or divided dose	<b>Orthographic similarities</b> - Both names begin with “F” - Both names have an upstroke in the middle of the name - Both names are similar in length  <b>Product characteristic overlaps</b> - Strength (numerical overlap and obtainable)	<b>Orthographic differences</b> - Fulyzaq has multiple downstrokes vs. Fulvicin has no downstrokes - Fulyzaq does not have a modifier vs. Fulvicin is available in two forms, U/F and P/G, and must be written with a modifier to differentiate between the two products  <b>Product characteristic differences</b> - none

No.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
8.	<b>Folicet</b> (Folic acid) - Folicet is off market, generic available  - 1 mg oral tablet  - 1 mg to 15 mg by mouth once daily	<b>Phonetic similarities</b> - Both names begin with the sound “F” - Both names have three syllables - Both names have the same second syllable sound, “ee”  <b>Product characteristic overlaps</b> - Strength (both single strength) - Dose (one tablet) - Route of administration (once daily)	<b>Phonetic differences</b> - The final syllable in Fulyzaq is emphasized and has the sound “ack” vs. the first syllable in Folicet is emphasized and the last syllable has the sound “eht”  <b>Product characteristic differences</b> - Frequency of administration (twice daily vs. once daily)
9.	<b>Folotyn</b> (Pralatrexate)  - 20 mg/mL, 40 mg/2 mL injection solution  - 30 mg/m <sup>2</sup> intravenous injection over 3-5 minutes once weekly for 6 weeks	<b>Orthographic similarities</b> - Both names begin with “F” - Both names have an upstroke in the middle of the name - Both names have a downstroke in the middle of the name - Both names are similar in length  <b>Product characteristic overlaps</b> - none	<b>Orthographic differences</b> - Fulyzaq has a downstroke at the end of the name and the middle vs. Folotyn has one downstroke toward the end of the name - Fulyzaq has two upstrokes vs. Folotyn has three upstrokes  <b>Product characteristic differences</b> - Dose (one tablet or 125 mg vs. 30 mg/m <sup>2</sup> , weight based dose) - Frequency of administration (twice daily vs. once weekly)
10.	<b>Jalyn</b> (Dutasteride and Tamsulosin)  - 0.5 mg/0.4 mg oral capsule  - One capsule by mouth once daily	<b>Orthographic similarities</b> - “F” and “J” appear similar when scripted - Both names have an upstroke in the middle of the name - Both names have a downstroke in the middle of the name  <b>Product characteristic overlaps</b> - Strength (both single strength) - Route of administration (oral) - Dosage form (oral solid)	<b>Orthographic differences</b> - Fulyzaq has multiple downstrokes vs. Jalyn has one downstroke giving the name a different shape when scripted - Fulyzaq has seven letters vs. Jalyn has five letters making the name appear shorter when scripted  <b>Product characteristic differences</b> - Frequency of administration (twice daily vs. once daily)

No.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
11.	<b>Pertzye</b> (Lipase, Protease, and Amylase)  - 8,000 Units/ 28,750 Units/ 30,250 Units, 16,000 Units/ 57,500 Units/ 60,500 Units capsules  - 500 lipase units/kg to 3500 lipase units/kg by mouth per meal three times daily	<b>Orthographic similarities</b> - “P” and “F” appear similar when scripted - Both names have an upstroke in the middle of the name - Both names have downstroke in the middle of the name  <b>Product characteristic overlaps</b> - Route of administration (oral) - Dosage form (solid oral)	<b>Orthographic differences</b> - Fulyzaq ends with a downstroke vs. Pertzye has one letter that follows the final upstroke giving the name a different shape - Fulyzaq does not have a cross-stroke in the middle of the name vs. Pertzye has a cross-stroke in the middle of the name  <b>Product characteristic differences</b> - Strength (125 mg, single strength, not required on prescription vs. 8,000 Units/ 28,750 Units/ 30,250 Units, 16,000 Units/57,500 Units/ 60,500 Units capsules, no mg overlap or numerical similarity) - Frequency of administration (twice daily vs. three times daily with food)
12.	<b>Zolyse</b> (Chymotrypsin) - Not marketed, no generic available  - 750 Units/mL ophthalmic solution  - Injection into posterior chamber of eye to irrigate	<b>Orthographic similarities</b> - Both names have an upstroke in the middle of the name - Both names have a downstroke in the middle of the name  <b>Product characteristic overlap</b> - none	<b>Orthographic differences</b> - Fulyzaq has multiple downstrokes vs. Zolyse has one downstroke giving the name a different shape when scripted  <b>Product characteristic differences</b> - Dose (once tablet or 125 mg vs. mL to irrigate area) - Frequency of administration (twice daily vs. ophthalmic surgery)

No.	<b>Proposed Name:</b> <b>Fulyzaq</b>  <b>Dosage Form:</b> <b>Tablet</b>  <b>Strength: 125 mg</b>  <b>Usual Dose: One tablet by mouth twice daily</b>	<b>Causes of Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion could be multiple</b>	<b>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</b>
13.	<b>Fura-mag</b> (Magnesium fumarate)  - 140 mg oral tablet  - One tablet by mouth one to three times daily	<b>Orthographic similarities</b> - Both names begin with "F" - Both names ends with a downstroke - Both names are similar in length  <b>Product characteristic overlap</b> - Strength (both single strength) - Frequency of administration (twice daily) - Route of administration (oral) - Dosage form (tablet)	<b>Orthographic differences</b> - Fulyzaq has two upstrokes vs. Fura-mag has one upstroke giving the name a different shape when scripted - Fulyzaq has at least one downstroke in the middle of the name (two, if the "z" is scripted) vs. Fura-mag has no downstrokes in the middle of the name giving the name a different shape  <b>Product characteristics differences</b> - none

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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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DENISE V BAUGH  
11/02/2012

LUBNA A MERCHANT  
11/02/2012