CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202155Orig1s000

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:	October 22, 2012
Reviewer:	Morgan Walker, Pharm.D., M.B.A. Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, Pharm.D. BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strength(s):	Eliquis (Apixaban) Tablets 2.5 mg and 5 mg
Application Type/Number:	NDA 202155
Applicant:	Bristol Myers Squibb
OSE RCM #:	2012-2339

*** 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, Eliquis (Apixaban) Tablets, 2.5 mg and 5 mg, 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, Eliquis, acceptable in OSE Review #2011-3807, dated December 6, 2011.

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 #2011-3807. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our re-evaluation did not alter our conclusion for OSE Review # 2011-3807. The searches of the databases yielded one new name ([redacted] (b) (4) thought to look or sound similar to Eliquis 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 Eliquis and lead to medication errors. This analysis determined that the name similarity between Eliquis and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

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 18, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on October 18, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Cardiovascular and Renal Products (DCRP) 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 Cherye Milburn, OSE project manager, at 301-796-2084.

4 REFERENCES

1. **OSE Reviews: RCM #2011-3807.**

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

	Proposed name: **Eliquis (Apixaban) Tablets** **2.5 mg and 5 mg** **Usual Dose:** **2.5 mg to 5 mg orally twice daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1	(b) (4)		

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/s/

MORGAN A WALKER
10/22/2012

IRENE Z CHAN
10/22/2012

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--Final

Date:	April 4, 2012
Reviewer:	Morgan Walker, Pharm.D., M.B.A. Division of Medication Error Prevention and Analysis
Acting Team Leader	Chi-Ming (Alice) Tu, Pharm.D. Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, R.Ph. Division of Medication Error Prevention and Analysis
Drug Name and Strength(s):	Eliquis (Apixaban) Tablets 2.5 mg, 5 mg
Application Type/Number:	NDA 202155
Applicant/sponsor:	Bristol-Myers Squibb
OSE RCM #:	2012-541-1

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Eliquis (Apixaban) Tablets, 2.5 mg and 5 mg, is written in response to the anticipated approval of this NDA 202155 within 90 days from the date of this review. DMEPA found the proposed name, Eliquis, acceptable in OSE Review 2011- 3807 dated December 6, 2011.

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 2011- 3807. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name ((b) (4) thought to look or sound similar to Eliquis 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 (b) (4) and lead to medication errors. This analysis determined that the name similarity between Eliquis and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

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 March 26, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on March 29, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Cardiovascular and Renal Products (DCRP) 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 Phuong (Nina) Ton, OSE project manager, at 301-796-1648.

4 REFERENCES

1. **OSE Review 2011-3807, Proprietary Name Review for Eliquis**

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: FMEA Table

Proposed name: Eliquis (Apixaban) Strengths and Dosage form: 2.5 mg and 5 mg oral tablets Usual Dose: 2.5 mg or 5 mg twice daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
(b) (4)		

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/s/

MORGAN A WALKER
04/04/2012

CHI-MING TU
04/04/2012

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:	December 6, 2011
Reviewer(s):	Morgan Walker, Pharm.D., M.B.A., Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Irene Z. Chan, Pharm.D., BCPS, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh., Director Division of Medication Error Prevention and Analysis
Drug Name(s):	Eliquis (Apixaban) Tablets 2.5 mg and 5 mg
Application Type/Number:	NDA 202155
Applicant/sponsor:	Bristol-Myers Squibb Company
OSE RCM #:	2011- 3807

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Eliquis, 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

DMEPA previously completed a proprietary name review for the proposed proprietary name, Eliquis, during the IND phase (OSE RCM # 2010-654) dated September 9, 2010. The name was found acceptable at that time. Since our previous review, the product characteristics have changed to include a 5 mg dose and strength.

1.2 PRODUCT INFORMATION

The Applicant/Sponsor provided the following product information for Eliquis as part of their October 4, 2011 submission.

- Established Name: Apixaban
- Indication of Use: Prevention of stroke and systemic embolism in patients with atrial fibrillation
- Route of administration: Oral
- Dosage form: Tablets
- Dose: The recommended dose is 5 mg twice daily, or 2.5 mg twice daily in patients with at least 2 of the following: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine ≥ 1.5 mg/dL
- How Supplied: Bottles of 60 and 180; unit dose blister cards of [redacted] (b) (4); and professional samples (5 mg tablet blister cards of 14 tablets per card)
- Storage: Store at 20°C to 25°C; excursions permitted between 15°C to 30°C

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) 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 evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

The October 7, 2011 United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name is comprised of a single word, and does not contain any components (i.e. a modifier, route of administration, dosage form, etc) that can contribute to medication error or render the name unacceptable.

2.2.4 FDA Name Simulation Studies

Thirty-one practitioners participated in DMEPA's prescription studies. Four outpatient respondents ended the name Eliquis with an 'r' instead of an 's'. One outpatient respondent ended the name with a 'z' instead of an 's'. 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, October 13, 2011 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to the proposed name at the initial phase of the 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 name, Eliquis. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Eliquis identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also included the names identified from the FDA Prescription Simulation or by [redacted] (b) (4) that were not previously identified by DMEPA and require further evaluation.

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Adagen	FDA	Eliphos	FDA	Folgard Tablet	FDA
Aloprim	FDA	Elixicon	FDA	Climara	FDA
Atripla	FDA	Elixomin	FDA	Clindagel	FDA
Atryn	FDA	Elizac	FDA	EpiQuin	FDA
Clorpres	FDA	Elspar	FDA	Alesse	External
Diquinol	FDA	Flagyl	FDA	aliskiren	External

Elaprase	FDA	Clinoril	FDA		
Elase	External	Micardis	External		
Eldepryl	External	Nyquil	External		
Equagesic	External	Aloxi	External		
Equanil	External				
Excedrin	External				
Lasix	External				
Levaquin	External				
Sound Similar					
Look and Sound Similar					
Eldoquin	Both	Elimite	Both		
Elocon	Both	Elitek	Both		
Elavil	Both				
Elidel	Both				
Eligard	Both				

Our analysis of the 37 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics. We determined the 37 names will not pose a risk for confusion as described in Appendices D and E. Additionally, DMEPA re-reviewed previously identified names in the IND due to changes in the product characteristics. We determined the previous names reviewed in the IND also do not pose a risk for confusion with Eliquis.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated these findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on October 28, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on November 7, 2011, they stated no additional concerns with the proposed proprietary name, Eliquis.

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 Nina Ton, OSE project manager, at 301-796-1648.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Eliquis, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 4, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

1. ***OSE Review:***

   RCM # 2010-654: Proprietary Name Review for Eliquis. September 9, 2010

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

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

3. ***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.

4. ***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.

5. ***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.

6. ***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.

7. ***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.

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

14. ***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.

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

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

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

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

17. Medical Abbreviations Book

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2] The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

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

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
	Similar spelling	Identical prefix	• Names may appear similar

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

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

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and

Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary

name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual***

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

practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike"

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. 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, Eliquis	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'E'	F	Any vowel
Lowercase 'e'	a, c, i, l,	Any vowel
Lowercase 'l'	b, e, t	N/A
Lowercase 'i'	a, c, e, l	Any vowel
Lowercase 'q'	g, j, y, z	c, k
Lowercase 'u'	a, n, o, r, y	Any vowel
Lowercase 'i'	a, c, e, l	Any vowel
Lowercase 's'	n, r, v	c, z

Appendix C: Prescription Simulation Samples and Results

Figure 1. Eliquis Study (Conducted on 10/14/2011)

Handwritten Requisition Medication Order	Verbal Prescription
Inpatient Medication Order: Eliquis 5mg 1 po bid	Eliquis 5 mg Take one tablet by mouth twice a day Disp: #60
Outpatient Prescription: Eliquis 5mg #60 1 tab po BID	

FDA Prescription Simulation Responses: 10/14/2011 (n = 31).

INPATIENT	VOICE	OUTPATIENT
ELIQUID (1)	ELAQUIS (1)	ELIQUIR (4)
ELIQUIS (13)	ELEQUIS (1)	ELIQUIS (4)
	ELIQUIS (1)	ELIQUIZ (1)
	ELIQUISS (1)	
	ELIQUOS (1)	
	ELLIQUIS (1)	
	ELLOQUIS (1)	
	ELOQUIS (1)	

Appendix D: Names eliminated from further evaluation for reasons listed below (n=22)

	Proprietary Name	Similarity to Eliquis	Active Ingredient	Reason Eliminated
1	aliskiren	Look Alike	N/A	Lacking orthographic or phonetic similarity
2	Aloxi	Look Alike	Palonosetron	Lacking orthographic or phonetic similarity
3	Atripla	Look Alike	Efavirenz, Emtricitabine, and Tenofovir	Lacking orthographic or phonetic similarity
4	Atryn	Look Alike	Antithrombin	Lacking orthographic or phonetic similarity
5	Climara	Look Alike	Estradiol	Lacking orthographic or phonetic similarity
6	Clindagel	Look Alike	Clindamycin	Lacking orthographic or phonetic similarity
7	Clinoril	Look Alike	Sulindac	Lacking orthographic or phonetic similarity
8	Diquinol	Look Alike	Idursulfase	Discontinued; available as Yodoxin
9	Elase	Look Alike	Fibrinolysin/desoxyribonuclease	Lacking orthographic or phonetic similarity
10	Eldepryl	Look Alike	Selegiline	Lacking orthographic or phonetic similarity
11	Elimite	Look Alike	Permethrin	Lacking orthographic or phonetic similarity
12	Elitek	Look Alike	Rasburicase	Lacking orthographic or phonetic similarity
13	Elixicon	Look Alike	Theophylline Suspension	Lacking orthographic or phonetic similarity
14	Elixomin	Look Alike	Theophylline	Lacking orthographic or phonetic similarity
15	Elizac	Look Alike	Fluoxetine	Lacking orthographic or phonetic similarity
16	Equagesic	Look Alike	Aspirin/Meprobamate	Lacking orthographic or phonetic similarity

17	Excedrin	Look Alike	Acetaminophen/Aspirin/Caffeine	Lacking orthographic or phonetic similarity
18	Folgard Tablet	Look Alike	B-Complex Formula	Lacking orthographic or phonetic similarity
19	Lasix	Look Alike	Furosemide	Lacking orthographic or phonetic similarity
20	Levaquin	Look Alike	Levofloxacin	Lacking orthographic or phonetic similarity
21	Micardis	Look Alike	Telmisartan	Lacking orthographic or phonetic similarity
22	Nyquil	Look Alike	Acetaminophen, Dextromethorphan, Doxylamine, Pseudoephedrine	Lacking orthographic or phonetic similarity

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
1	Adagen (Pegademase Bovine) Strength: 250 units/mL Dose: Infants and Children: Dose given every 7 days, 10 units/kg the first dose, 15 units/kg the second dose, and 20 units/kg the third dose; maintenance dose: 20 units/kg/week; maxiumum single dose: 30 units/kg	Orthographic similarities: Both names have a downstroke in the same position ('q' vs. 'g'). Both names have an upstroke in the same position ('l' vs. 'd'). Overlapping product characteristics: Dosage: 2.5 vs. 250	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Prefixes differ (Ada vs. Eli) The string 'quis' appears to be longer than the string 'gen' Differentiating product characteristics: Dose: 10 units/kg to 20 units/kg vs. 2.5 mg to 5 mg BID Frequency: Weekly vs. BID
2	Alesse (Ethinyl Estradiol and Levonorgestrel) Strength: Ethinyl estradiol 0.02 mg and levonorgestrel 0.1 mg Dose: Take 1 tablet daily	Orthographic similarities: Both names have the same upstroke in similar positions ('l'). Overlapping product characteristics: Dosage form: Tablet Route of administration: oral	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Alesse does not contain a downstroke. Alesse appears shorter than Eliquis when scripted. Differentiating product characteristics: Strength: 0.02 mg and 0.1 mg (or omitted because of single strength) vs 2.5 mg to 5 mg

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
3	Aloprim (Allopurinol) Strength: 500 mg Dose: 200 to 400 mg/m^2/day (maximum: 600 mg/day) beginning 1 to 2 days before chemotherapy	Orthographic similarities: Both names have the same upstroke in similar positions ('l'). Both names have a downstroke in similar positions ('q' vs. 'p'). Overlapping product characteristics: None	Product characteristics listed below minimize the potential for confusion: Dose: 200 to 400 mg/m^2 vs. 2.5 to 5 mg
4	Clorpres (Clonidine and Chlorthalidone) Strength: Clonidine 0.1 mg and chlorthalidone 15 mg; Clonidine 0.2 mg and chlorthalidone 15 mg; Clonidine 0.3 mg and chlorthalidone 15 mg Dose: 1 tablet 1-2 times/day; maximum: 0.6 mg clonidine and 30 mg chlorthalidone	Orthographic similarities: Both names have the same upstroke in similar positions ('l'). Both names have a downstroke in similar positions ('q' vs. 'p'). Both names end with the letter 's'. Overlapping product characteristics: Dosage form: tablet Route of administration: oral Dose: one tablet	Product characteristics listed below minimize the potential for confusion: Strength: 0.1 mg/15 mg; 0.2 mg/15 mg; 0.3 mg/15 mg vs. 2.5 mg to 5 mg

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
5	Elaprase (Idursulfase) Strength: 6 mg/3 mL injection Dose: Inject 0.5 mg/kg intravenously over 1 to 3 hours every week	Orthographic similarities: Both names begin with the string 'El'. Both names contain a downstroke in similar places. Overlapping product characteristics: None	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: The string after the downstroke is different and shorter in Eliquis (uis vs. rase) Differentiating product characteristics: Dose: 0.5 mg/kg vs 2.5 mg to 5 mg
6	Elavil (Amitriptyline) Strength: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg Dose: 50 mg to 150 mg/day single dose at bedtime or in divided doses; dose may be gradually increased up to 300 mg/day	Orthographic similarities: Both names begin with the string 'El'. Overlapping product characteristics: Numerical similarity: 2.5 mg vs. 25 mg and 50 mg vs. 5 mg Route of administration: oral Frequency: Elavil can be given in divided doses, such as BID Dosage form: tablet *The name Elavil is discontinued however generics are available and	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Elavil contains an upstroke at the end of the name 'l', whereas Eliquis does not. Elavil does not contain a downstroke.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
		prescribers may still write the name Elavil when writing a prescription.	
7	Eldoquin (Hydroquinone) Strength: 2% cream Dose: Apply to affected 2 times daily or as directed	Orthographic similarities: Both names begin with the string 'El'. Both names contain the string 'qui'. Overlapping product characteristics: Frequency: BID	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Eldoquin contains an additional upstroke letter ('d') in the third letter position, which is absent in Eliquis. Differentiating product characteristics: Dose: One application vs. 2.5 mg, 5 mg or one tab Strength: Single strength 2% vs. multiple strength which will be required on the prescription. No overlap in strength.
8	Elidel (Pimecrolimus) Strength: 1% cream Dose: Apply a thin layer to affected area 2 times daily	Orthographic similarities: Both names begin with the string 'Eli'. Overlapping product characteristics: Frequency: BID	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Elidel contains 2 additional upstroke letters ('d' and 'l') whereas Eliquis contains a downstroke letter ('q'), giving the names different shape. Differentiating product characteristics: Strength: Single strength 2% vs. multiple strength which will be required on the

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
			prescription. No overlap in strength. Dose: A thin layer vs. 2.5 mg to 5 mg po
9	Eligard (Leuprolide) Strength: 7.5 mg, 22.5 mg, 30 mg, 45 mg injection Dose: Inject 7.5 mg, 22.5 mg, 30 mg, or 45 mg subcutaneously every 1, 3, 4, or 6 months	Orthographic similarities: Both names begin with the string 'Eli'. Both names contain a downstroke in similar positions Overlapping product characteristics: None	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Eligard contains an upstroke letter 'd' at the end of the name which is absent in Eliquis giving the names a different shape. Differentiating product characteristics: Strength: 7.5 mg, 22.5 mg, 30 mg, 45 mg vs. 2.5 mg or 5 mg
10	Elspar (Asparaginase) Strength: 10,000 units for injection Dose: Inject 1,000 units/kg/day x 10 days starting on Day 22 of treatment period Inject 6,000 units/m^2 intramuscularly on days 4, 7, 10, 13, 16, 19, 22, 25, and 28 of the treatment period	Orthographic similarities: Both names begin with the string 'El'. Both names have a downstroke. Overlapping product characteristics: None	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: The string after the downstoke in Elspar appears shorter than in Eliquis when scripted. Differentiating product characteristics: Dose: 1,000 units/kg or 6,000 units/m^2 vs. 2.5 mg and 5 mg Strength: Elspar is a single strength product vs. Eliquis having multiple strengths, no overlap in strength

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
11	EpiQuin Micro (Hydroquinone Microspheres) (discontinued 3/11/2010, EpiQuin Micro Pump is available) Strength: 4% cream Dose: Apply to affected area twice daily or as directed	Orthographic similarities: Both names start with the letter 'E' and have the same string 'qui'. Overlapping product characteristics: Frequency: BID	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: The second letter of EpiQuin is a downstroke (lowercase 'p') while the second letter in Eliquis is an upstroke (lowercase 'l'). Differentiating product characteristics: Strength: 4% vs. 2.5 mg or 5 mg
12	Flagyl (Metronidazole) Strength: 250 mg, 375 mg, 500 mg tablets; 500 mg/100 mL injection Dose: Take 1 tablet orally 3 times daily Take 2 g orally once Take 1 g orally every 12 hours x 2 doses; 7.5 mg/kg intravenously every 6 hours	Orthographic similarities: Both names have upstrokes 'l' in the same position. Both names have downstrokes ('g' in Flagyl and 'q' in Eliquis) in the same position. Overlapping product characteristics: Oral administration Dosage form: tablet	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Flagyl contains an additional downstroke ('y') and upstroke ('l') at the end of the name, which is absent in Eliquis, giving the name a different shape. Differentiating product characteristics: Dose: 250 mg, 375 mg, 500 mg, 1 gram, or 2 gram vs 2.5 mg or 5 mg
13	Eliphos	Orthographic similarities: Both names contain the	Orthographic differences in the names along with variations in product characteristics listed

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**		**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion		**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
	(Calcium Acetate) Strength: 667 mg tablet Dose: Take 2 to 4 tablets orally with meals	same string 'Eli'. Both names contain downstrokes in the same position ('p' in Eliphos and 'q' in Eliquis) Both names end with the letter 's' Overlapping product characteristics: Oral administration Dosage form: oral tablet	below minimize the potential for confusion. Orthographic differences: Eliphos contains an additional upstroke 'h' immediately following the downstroke. Differentiating product characteristics: Dose: 2 to 4 tablets vs. 1 tablet Strength: 667 mg vs. 2.5 mg or 5 mg
14	Elocon (Mometasone Furoate) Strength: 0.1% cream, ointment, lotion Dose: Apply a thin film to affected area once daily	Orthographic similarities: Both names contain the same string 'El'. Overlapping product characteristics: None	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion. Orthographic differences: Eliquis contains a downstroke letter 'q' in the middle of the name, which is absent in Elocon giving the name a different shape. Differentiating product characteristics: Strength: No overlap in strength (0.1% vs. 2.5 mg or 5 mg) Dose: Thin film vs one tablet or 2.5 mg or 5 mg
15	Equanil (Meprobamate) Strength: 200 mg,	Orthographic similarities: Both names contain the string 'qu'.	Orthographic differences in the names along with variations in product characteristics listed below minimize the potential for confusion.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors (n =15).

PROPOSED NAME: **Eliquis** **(Apixaban)**	**STRENGTH:** **2.5 mg and 5 mg**	**USUAL DOSE:** **2.5 mg to 5 mg po BID**
FAILURE MODE: Name Confusion	**CAUSES:** (Potential reasons for name confusion that could lead to medication error)	**PREVENTION OF FAILURE MODE** (Reasons why the risk of medication error is minimized)
400 mg tablets Dose: Take 1 tablet orally 3 to 4 times daily	Overlapping product characteristics: Oral administration Dosage form: tablets	Orthographic differences: Eliquis contains an upstroke 'l' and an additional letter in front of the 'qu' string. Equanil contains an upstoke at the end of the name. Differentiating product characteristics: Strength: 200 mg or 400 mg vs. 2.5 mg and 5 mg

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/s/

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12/19/2011

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