CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206316Orig1Orig2s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	March 14, 2014
Reviewer(s):	Denise V. Baugh, PharmD, BCPS Division of Medication Error Prevention and Analysis
Team Leader	Lisa V. Khosla, PharmD, MHA Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	Savaysa (Edoxaban) Tablets 15 mg, 30 mg, 60 mg
Application Type/Number:	NDA 206316 (IND 077254)
Applicant/Sponsor:	Daiichi-Sankyo
OSE RCM #:	2014-16829

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

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Savaysa, 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

A request for Proprietary name Review was submitted by the Sponsor on December 9, 2010 for Lixiana under IND 077254. In OSE Review #2010-2645 dated June 2, 2011, the Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Lixiana, vulnerable to name confusion with the proprietary names Gen-Xene, Lexapro, Loxapine, and Loxitane. The Sponsor was notified of our decision in writing on June 7, 2011. The Sponsor submitted a request for reconsideration of the proposed proprietary name, Lixiana, on November 30, 2011. On May 30, 2012, a denial of the reconsideration was sent to the Sponsor to uphold the original decision of rejecting the name Lixiana.

The proposed name was submitted to IND 077254, and was found to be acceptable (OSE Review # 2012-1940 dated January 16, 2013). This name will be re-reviewed under NDA 206316 and is the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 21, 2014 proprietary name submission.

- Active Ingredient: Edoxaban
- Indication of Use: 1) reduction in the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (NVAF); treatment of deep vein thrombosis (DVT); 3) treatment of pulmonary embolism (PE) [redacted (b) (4)]
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 15 mg, 30 mg, 60 mg
- Dose and Frequency: 60 mg once daily; 30 mg once daily [redacted (b) (4)] low body weight (< 60 kg); or concomitant use of P-glycoprotein inhibitors [redacted (b) (4)] To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.
- How Supplied: bottles of 30 count, 90 count, and 500 count tablets [redacted (b) (4)] hospital unit dose blister; package of 10 tablets [redacted (b) (4)]
- Storage: 20°C to 25°C (68°F to 77°F)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The January 30, 2014 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, Savaysa, has no specific derivation or intended meaning. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.4 FDA Name Simulation Studies

Seventy-four practitioners participated in DMEPA's prescription studies. One participant in the voice mail study commented that the proposed proprietary name, Savaysa, sounded like "Zavesa" which sounds similar to the marketed name, Zavesca. Another voice mail study participant interpreted the name as "Zypresa" which sounds similar to the marketed name, Zyprexa. The remaining misinterpretations did not overlap with any currently marketed products or any products in the pipeline.

The majority of misinterpretations included mistaking the 'S' for a 'Z', C, or 'G'; mistaking the first letter 'a' for the letter 'e' or 'o'; and mistaking the 'v' for an 'n', 'r', or 'w'. Additionally, most of the voice mail participants did not identify the letter 'y' in their interpretations. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 28, 2014 e-mail, the Division of Cardiovascular and Renal Products (DCRP) and the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the 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, Savaysa. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Savaysa identified by the Primary Reviewer (PR), the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation Studies (Rx Studies) or by Drug Safety Institute, Inc. (DSI) not identified by DMEPA and require further evaluation.

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Sarafem	FDA	(b) (4) ***	FDA	Saxenda***	FDA
Kapvay	FDA	Garamycin	FDA	Sensipar	FDA
Sumycin	FDA	Anaspaz	FDA		
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Zyprexa	Rx Studies				
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Savella	FDA/DSI	Savaysa	FDA	Aventyl	DSI
Canasa	DSI	Desipramine	DSI	Doxepin	DSI
Duloxetine	DSI	Effexor	DSI	Fiv-Asa	FDA/DSI
Lovaza	DSI	Neurontin	DSI	Nortriptyline	DSI
Pamelor	DSI	Sancuso	DSI	Sangcya	DSI
Sinequan	DSI	Venlafaxine	DSI	Vyvanse	DSI
Zavesca	DSI/Rx Studies				

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Our analysis of the twenty-eight names contained in Table 1 determined 28 names will not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) and the Division of Hematology Products (DHP) via e-mail on February 19, 2014. 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) and the Division of Hematology Products (DHP) on February 24, 2014 (DCRP) and March 11, 2014 (DHP) respectively, they stated no additional concerns with the proposed proprietary name, Savaysa.

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 Karen Bengtson, OSE Project Manager for the Division of Cardiovascular and Renal Products, at 301-796-3338.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 21, 2014 submission are altered, the name must be resubmitted for review.

4 REFERENCES

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

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

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. Drug Facts and Comparisons, online version, St. Louis, MO (***http://factsandcomparisons.com***)

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

9. ***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.

10. ***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.

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

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

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

18. Dogpile (www.dogpile.com)

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

19. Natural Standard (http://www.naturalstandard.com)

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

APPENDICES

Appendix A

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

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

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

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

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

[2] 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.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar 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

[3] 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 posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

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

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

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

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

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

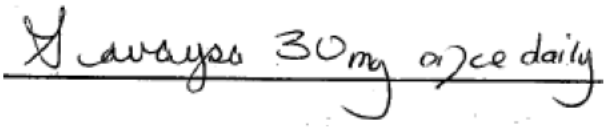
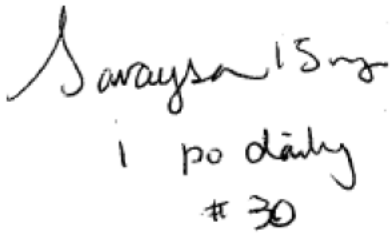
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Savaysa	**Scripted May Appear as**	**Spoken May Be Interpreted as**
Capital 'S'	R, P, L, D, A, C, X, G, 5, Z, V, K	Z, X, C
Lower case 'a'	el, ci, cl, d, o, u, i, e	any vowel
Lower case 'v'	r, u, w, n	f
Lower case 'y'	f, p, u, v, x, Z, g, z, j	e, i, u, silent
Lower case 's'	d, f, k, p, t, u, v, y, G, 5, g, n, r, c	x, z, c
Letter Strings		
Sa		ca
vay		vey, vei, fa, fe,
sa		sah, za, xa,

Appendix C: Prescription Simulation Samples and Results

Figure 1. Savaysa Study (Conducted on February 3, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	"Savaysa 15 mg, Take one orally daily, dispense quantity # 30"
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Savaysa

As of Date 2/5/2014

268 People Received Study

74 People Responded

Study Name: Savaysa

OUTPATIENT	VOICE	INPATIENT
SANAYSA (2)	CEVASA (2)	GAVAYSC (1)
SARAYSA (8)	SAVESA (1)	GAVAYSO (2)
SARAYSAN (1)	SERVASA (1)	GIAVAYSO (1)
SARAYSN (1)	SEVASA (1)	SAVAYSA (8)
SAVAYSA (14)	SEVESA (1)	SAVAYSO (10)
SAVAYSN (1)	SOVARA (1)	SAYVASO (1)
SAWAYSA (1)	SOVASA (1)	
SAWYSA (1)	ZAVASA (2)	
	ZAVAYSA (1)	
	ZAVESA (5)	
	ZEVAISA (1)	
	ZEVASA (1)	
	ZEVESA (2)	
	ZIVACA (1)	
	ZYPRESA (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 Savaysa	Failure preventions
1.	Desipramine	Desipramine	Look & Sound	The pair have sufficient orthographic and phonetic differences
2.	Pamelor	Nortriptyline	Look & Sound	The pair have sufficient orthographic and phonetic differences
3.	Vyvanse	Lisdexamfetamine Dimesylate	Look & Sound	The pair have sufficient orthographic and phonetic differences
4.	Nortriptyline	Nortriptyline	Look & Sound	The pair have sufficient orthographic and phonetic differences
5.	Neurontin	Gabapentin	Look & Sound	The pair have sufficient orthographic and phonetic differences
6.	Effexor	Venlafaxine Hydrochloride	Look & Sound	The pair have sufficient orthographic and phonetic differences
7.	Venlafaxine	Venlafaxine Hydrochloride	Look & Sound	The pair have sufficient orthographic and phonetic differences
8.	Duloxetine	Duloxetine	Look & Sound	The pair have sufficient orthographic and phonetic differences
9.	Aventyl	Nortriptyline Hydrochloride	Look & Sound	The pair have sufficient orthographic and phonetic differences
10.	Doxepin	Doxepin	Look & Sound	The pair have sufficient orthographic and phonetic differences
11.	Savaysa	Edoxaban	Look & Sound	Subject of this review
12.	Kapvay	Clonidine	Look	The pair have sufficient

		Hydrochloride		orthographic differences
13.	(b) (4)***	(b) (4)	Look	DMEPA found the proposed name, (b) (4) unacceptable (OSE Review # 2009-2410 dated May 27, 2010) due to the inclusion of the USAN stem (b) (4) in its name. The Applicant submitted the alternate proprietary name, (b) (4) to IND (b) (4) which was found to be acceptable (OSE Review# 2010-1411 dated December 15, 2010).
14.	Fiv-Asa	Mesalamine	Look and Sound	The pair have sufficient phonetic and orthographic differences

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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.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**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.	Sarafem (Fluoxetine) Capsule/Tablet 10 mg, 20 mg *Usual dose*: 20 mg to 60 mg once daily	Orthographic similarity stems from sharing the same 1st, 2nd, and 4th letters ('Sa' and 'a') and the fact that the letters in the 3rd position may look similar in some handwriting samples ('n' vs. 'r'). Overlapping product characteristics include the dose (potentially 60 mg) and the frequency of administration (once daily). Additionally, 30 mg is achievable with three 10 mg capsules/tablets.	The marketed name, Sarafem, contains one up stroke ('f') and the proposed proprietary name, Savaysa has one down stroke ('y') giving these names different shapes. Additionally, the last letter in Sarafem is the 'm' which is wider than the last letter in Savaysa ('a').

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Saxenda*** (Liraglutide) Injection 6 mg/mL *Usual dose*: Initiate with 0.6 mg subcutaneously once daily and increase dose by 0.6 mg each week up to 3 mg per day	Orthographic similarity stems from sharing the 1st two letters ('Sa') and the last letter ('a') in their names. Additionally, the letters in the 3rd positions within these names may look similar in some handwriting styles ('x' vs. 'v'). Overlapping product characteristics include the frequency of administration (once daily). Additionally, there is numerical similarity in their doses (0.6 mg vs. 60 mg and 3 mg vs. 30 mg).	The proposed proprietary name, Saxenda***, contains one up stroke ('d') in contrast to the proposed proprietary name, Savaysa, which has one down stroke ('y') giving these names different shapes. Although Saxenda*** is available in a single dosage form (injection), the route of administration is likely to be stated since injections may be administered subcutaneously, intravenously, or intramuscularly. This information (route of administration) is necessary to give the medication as intended.

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No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Sumycin (Tetracycline) Tablet/Capsule 250 mg, 500 mg *Usual dose*: 250 mg to 500 mg every 6 hours or 500 mg to 1000 mg every 12 hours	Orthographic similarity stems from sharing the same first letter ('S') within their names and the fact that the letters in the 2nd position may look similar when written in some handwriting styles ('u' vs. 'a'). Additionally, both names have a single down stroke ('y') in similar locations within their names (4th vs. 5th positions) giving them similar shapes.	The letters which appear immediately before their down strokes (wide letter 'm' vs. the letter 'a') and the letter strings following ('cin' vs. 'sa') the down stroke ('y') look different when written and may help to distinguish this name pair. Differing product characteristics include their dose (250 mg or 500 mg vs. 15 mg, 30 mg, or 60 mg) and their frequency of administration (every 6 hours to 12 hours vs. once daily). Sumycin and Savaysa are available in multiple strengths and this information is needed to dispense/administer the medications as intended. There is no numerical overlap or similarity in their strengths.

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	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
4.	Garamycin (gentamicin) Ophthalmic Solution/Ointment: 3 % Injection: 10 mg/mL, 40 mg/mL Topical Ointment/Cream 0.1 % *Usual dose*: Ophthalmic Solution: Instill 1 to 2 drops into affected eye(s) every 4 hours Ophthalmic Ointment: Apply small amount to the affected eye(s) 2 to 3 times daily IV/IM: Administer 1 mg/kg to 1.7 mg/kg over 30 minutes every 8 hours *Topical Cream/Ointment*: Apply a small amount of cream/ointment gently to the lesions 3 or 4 times daily	Orthographic similarity stems from the similar appearance of their first ('G' vs. 'S') and their 3rd letter ('r' vs. 'v') in some handwriting styles and the fact that their 2nd and 4th letters are identical (both 'a'). Potentially overlapping product characteristic is the dose for Garamycin given parenterally and Savaysa (60 mg).	The letter(s) which precede and follow the down stroke in Garamycin and Savaysa look different when written. Specifically, the wide letter 'm' precedes the down stroke ('y') in the marketed name, Garamycin and the letter string 'cin' follows it. This is in contrast to the letter 'a' and the letter string 'sa' which precede and follow the down stroke ('y') respectively in the proposed name, Savaysa. Additionally, the name Garamycin is longer in length than Savaysa when written (9 letters vs. 7 letters). Garamycin (Gentamicin) is available in multiple dosage forms (ophthalmic solution/ointment, topical cream/ointment, or injection) and this information is needed to dispense/administer the medication as intended. Differing product characteristics include the route of administration (topically [into the eye or skin] or intravenously/intramuscularly) and the frequency of administration (2 to 3 times daily, every 4 hours).

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5.	Anaspaz Hyoscyamine Sulfate) Tablet: 0.125 mg *Usual dose*: 0.0625 mg to 0.125 mg every 4 hours as needed (maximum is 0.75 mg in 24 hours)	Orthographic similarity stems from the similar appearance of their first letters ('A' vs. 'S') in some handwriting styles. Additionally, both names have a single down stroke ('p' vs. 'y') in the same location within their names and both names are 7 letters in length	The last 2 letters in the marketed name, Anaspaz ('az') look different from the last 2 letters in the proposed name, Savaysa ('sa') when written. Additionally, the letters in the 2nd, 3rd, and 4th positions do not look similar when written ('nas' in Anaspaz vs. 'ava' in Savaysa) which may further distinguish this name pair. Savaysa is available in multiple strengths and this information is needed to dispense/administer this medication prior to dispensing. There is no numerical similarity or overlap between the strengths. One differing product characteristic is the frequency of administration (every 4 hours as needed vs. once daily).

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Sensipar (Cinacalcet) Tablet 30 mg, 60 mg, 90 mg *Usual dose*: 30 mg to 180 mg once daily; 30 mg to 90 mg twice daily; 90 mg orally 3 to 4 times daily (regimens dependent upon diagnosis)	Orthographic similarity stems from sharing the same letter 'S' and the fact that both names have a single down stroke ('p' vs. 'y') in similar locations within their names. Additionally, the letters in the 2nd and 3rd positions may look similar in some handwriting styles ('en' vs. 'av'). Overlapping product characteristics include their doses (30 mg and 60 mg), their routes of administration (oral), and (potentially) their frequency of administration (once daily).	The letter string which follows the down stroke in these names look different when written and may help to differentiate these names. Specifically, the letters 'ar' (in SensipAR) and 'sa' (in SavaySA) do not look similar when written. . Additionally, Sensipar has a dotted letter ('i') not found in Savaysa. Therefore, their infixes ('sip' vs. 'vay') also look different when written.

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Savella (Milnacipran) Tablet 12.5 mg, 25 mg, 50 mg, 100 mg *Usual dose*: 12.5 mg once daily up to 100 mg twice daily	Orthographic similarity stems from sharing the 1st two letters in their names ('Sa'). Phonetic similarity stems from the identical sounds of their prefixes ('Sa') and their suffixes ('a') when spoken and the fact that both names contain 3 syllables. Overlapping product characteristics include the route of administration (oral) and the frequency of administration (once daily). Additionally, the strength "50 mg" may be misinterpreted as "15 mg" (and vice versa) when spoken.	The marketed name, Savella includes two identical and sequential up strokes ('ll') in its name which gives it a different shape from the proposed name, Savaysa, which contains a single down stroke ('y'). Savella and Savaysa are available multiple strengths and this information is needed to dispense/administer the medications as intended. There is no numerical overlap or similarity in their strengths.

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8.	Canasa (Mesalamine, 5-ASA) Rectal Suppository 500 mg, 1000 mg *Usual dose*: 500 mg twice daily to 3 times daily or 1000 mg once daily at bedtime (retained in the rectum for 1 to 3 hours or more if possible)	Orthographic similarity stems from sharing the letter in the 2nd position ('a') and the last two letters ('sa') in their names. Additionally, the letters in the 3rd position look similar in some handwriting styles ('n' vs. 'v'). Phonetically, both of their suffixes end in 'sa' giving them identical sounds when spoken. Additionally, both names have 3 syllables. Since both products are available in a single dosage form, their routes of administration do not have to be identified on a prescription to dispense/administer the medication as intended.	The first letters in the marketed name Canasa ('c') and Savaysa ('S') do not look similar when written. Additionally, Savaysa contains a down stroke ('y') which gives this name a different shape from Canasa. Phonetically, the first letter in Canasa sounds like a 'k' and is a 'hard' sound versus the first letter in Savaysa is a soft sound ('s'). Additionally, the letter 'a' in their infixes may sound different when spoken. The 'a' produces a long sound in Savaysa, whereas it has a shorter, abrupt sound in Canasa Canasa and Savaysa are available multiple strengths and this information is needed to dispense/administer the medications as intended. There is no numerical overlap or similarity in their strengths.

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
9.	Lovaza (Fish Oil, Omega-3 Fatty Acids) Capsule 1 gram *Usual dose*: 4 gram once daily or 2 grams twice daily	Orthographic similiarty stems from the similar appearance of their first 2 letters ('Lo' vs. 'Sa') in some handwriting styles. Additionally, both names share the same letters in the 3rd, 4th, and last positions ('va' and 'a'). Phonetically, their suffixes sound identical when spoken ('za' vs. 'sa') and both names have 3 syllables. Overlapping product characteristics include the route of administration (oral) and the frequency of administration (once daily).	The proposed name, Savaysa includes a down stroke ('y') which gives this name a different shape from that of the marketed name, Lovaza. One differing product characteristic is the dose (2 grams to 4 grams vs. 15 mg, 30 mg, 60 mg). Savaysa is available in multiple strengths and this information is needed to dispense/administer this medication prior to dispensing. There is no numerical similarity or overlap between the strengths.

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	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
10.	Sinequan (Doxepin) Capsule 10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg *Usual dose*: 25 mg to 150 mg daily	Orthographic similarity stems from sharing the same first letter ('S') and having one down stroke in the same location (5th position) within their names ('q' vs. 'y'). Phonetically, both names begin with the letter 'S' which gives them an identical initial sound and both names have 3 syllables. Overlapping product characteristics include the route of administration (oral) and the frequency of administration (once daily). Additionally, numerical similarity exists (150 mg vs 15 mg) and the strength '50 mg' may be misinterpreted as '15 mg' when spoken.	There are 3 letters ('uan') which follow the down stroke ('q') in the marketed name, Sinequan in contrast to 2 letters ('sa') which follow the down stroke ('y') in Savaysa. This feature gives Sinequan a longer appearance when written.

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
11.	Zavesca (miglustat) capsule 100 mg *Usual dose*: 100 mg three times daily	Orthographically, their first letters may look similar in some handwriting styles ('Z' vs. 'S'). Additionally, both names share the same letters in the 2nd, 3rd, and 7th positions. Both names are 7 letters in length. Phonetic similarity stems from the similar sound of their first letter ('Z' vs. 'S') and the identical sound of the letters in the 2nd, 3rd, and 7th positions ('a', 'v', and 'a'). Additionally, both names contain 3 syllables. Overlap in product characteristics include the route of administration (oral) and (potentially) the frequency of administration (once daily).	The proposed name, Savaysa, includes a down stroke ('y') which gives this name a different shape from that of the marketed name, Zavesca. Phonetically, their infixes sound different. Savaysa has a long sound (SaVAYsa) versus the short sound belonging to Zavesca (ZaVEsca). One differing product characteristic is the frequency of administration (three times daily vs. once daily). Savaysa is available in multiple strengths and this information is needed to dispense/administer this medication prior to dispensing. There is no numerical similarity or overlap between the strengths.

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	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
12.	Sancuso (Granisetron) Transdermal Patch 3.1 mg/patch *Usual dose*: Apply a single patch 24 to 48 hours before chemotherapy; may be worn for up to 7 days (may remove a minimum of 24 hours after completion of chemotherapy)	Orthographic similarity stems from sharing the 1st two letters ('Sa') and their 6th letter ('a'). Additionally, the letters in the 3rd position of these names look similar in some handwriting styles ('n' vs. 'v'). Phonetically, the prefixes of both names sound similar because they share the same first 2 letters ('Sa'). Additionally, both names have 3 syllables. Since both products are available in a single dosage form, their routes of administration (topical versus oral) do not have to be identified on a prescription to dispense/administer the medication as intended.	The proposed name, Savaysa, includes a down stroke ('y') which gives this name a different shape from that of the marketed name, Sancuso. Phonetically, the infixes and suffixes of Savaysa and Sancuso sound different when spoken. The long sound of the 'a' vs. the 'u' is requires the mouth to be open to pronounce Savaysa and closed to pronounce Sancuso. Additionally, the last letter ('a') is a short sound in Savaysa versus the last letter in Sancuso ('o') has a long sound when spoken. Savaysa is available in multiple strengths and this information is needed to dispense/administer this medication prior to dispensing. There is no numerical similarity or overlap between the strengths.

No.	**Proposed name: Savaysa (Edoxaban)** **Dosage Form(s): Tablet** **Strength(s): 15 mg, 30 mg, 60 mg** **Usual Dose: 60 mg once daily; 30 mg once daily** (b) (4) **low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors** (b) (4) **To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	Sangcya (Cyclosporin) Oral Solution 100 mg/mL (Sangcya is no longer on the market, but generic products exist) *Usual dose*: 1.25 mg/kg orally twice daily (rheumatoid arthritis); 15 mg/kg as a single dose 4 to 12 hours before transplantation (heart, heart, or liver transplant rejection prophylaxis);	Orthographic similarity stems from sharing the 1st two letters ('Sa') and the last letter ('a') in their names. Phonetic similarity stems from sharing their first 2 letters ('Sa') and their last letter ('a') giving themsimilar sounds when spoken. Additionally, both names have 3 syllables. Overlapping product characteristics include the route of administration (oral) and, since Cyclosporin oral solution may be used in the pediatric population, the dose (60 mg) may overlap.	The marketed name, Sangcya includes two down strokes ('g' and 'y') versus one down stroke ('y') in the proposed name, Savaysa giving these names different shapes. The infix for Sangcya is likely pronounced as a long 'e' sound (e.g., sangCEEa) whereas the infix for the proposed name, Savaysa is likely to sound like a long 'a' sound (SaVAYsa).

No.	Proposed name: Savaysa (Edoxaban) Dosage Form(s): Tablet Strength(s): 15 mg, 30 mg, 60 mg Usual Dose: 60 mg once daily; 30 mg once daily (b) (4) low body weight (≤ 60 kg); or concomitant use of P-glycoprotein inhibitors (b) (4) To transition from Savaysa 30 mg to warfarin, reduce dose to 15 mg and begin warfarin concomitantly.	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
14.	Zyprexa (Olanzapine) Tablet 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg *Usual dose*: 2.5 mg to 20 mg once daily	Phonetic similarity stems from the similar sound of their first letters ('Z' vs. 'S') and their last two letters ('xa' vs. 'sa') when spoken. Additionally, both names have 3 syllables and the emphasis is traditionally on the 2nd one. Overlapping product characteristics include the route of administration (oral) and the frequency of administration (once daily). Additionally, they have overlapping strengths (15 mg) and achievable strengths (three 20 mg tablets to achieve 60 mg and three 10 mg tablets to achieve 30 mg)	The letter 'y' in the prefix for Zyprexa gives it a long sound (example, 'Zy' sounds like 'zEYE') versus the short sound of the letter 'a' in the prefix for Savaysa. Alternatively, their infixes sound different when spoken. The infix for Savaysa is long sounding (SaVAYsa) versus the short sound of the infix for Zyprexa.

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/s/

DENISE V BAUGH
03/14/2014

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