CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204251Orig1s000

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:	February 15, 2013
Reviewer:	Jung Lee, RPh Division of Medication Error Prevention and Analysis
Team Leader:	Jamie Wilkins Parker, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Simbrinza (Brinzolamide and Brimonidine Tartrate Ophthalmic Suspension), 1%/0.2%
Application Type/Number:	NDA 204251
Applicant/sponsor:	Alcon Research, Ltd
OSE RCM #:	2012-1974

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Simbrinza 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, Simbrinza, acceptable in OSE Review #2012-596 and 2012-1535 dated August 8, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2012-596 and 2012-1535. 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. The searches of the databases yielded two new names ((b) (4) and (b) (4)) thought to look or sound similar to Simbrinza and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary names could potentially be confused with Simbrinza and lead to medication errors. This analysis determined that the name similarity between Simbrinza 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 January 22, 2013. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on February 13, 2013 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Simbrinza, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Simbrinza, 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 Transplant and Ophthalmology Products 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 Karen Townsend, OSE project manager, at 301-796-5413.

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4 REFERENCES

1. ***Lee, J; OSE Review 2012-596 & 2012-1535, Proprietary Name Review of Simbrinza; August 8, 2012***

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. (n=2)

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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)		
2.			

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/s/

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02/15/2013

JAMIE C WILKINS PARKER
02/15/2013

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:	August 8, 2012
Reviewer:	Jung Lee, RPh Division of Medication Error Prevention and Analysis
Acting Team Leader:	Jamie Wilkins Parker, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Simbrinza (Brinzolamide and Brimonidine Tartrate Ophthalmic Suspension), 1%/0.2%
Application Type/Number:	IND 106293/NDA 204251
Applicant:	Alcon Research, Ltd
OSE RCM #:	2012-596/2012-1535

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Simbrinza, 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

On February 27, 2012, the Applicant submitted a request for review of the proposed proprietary name, Simbrinza under IND 106293. On July 3, 2012, the request for proprietary name review was submitted under NDA 204251.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 3, 2012 proprietary name submission.

- Active Ingredient: Brinzolamide and Brimonidine Tartrate
- Indication of Use: Reduction of intraocular pressure (IOP) for patients with open-angle glaucoma (OAG) and/or ocular hypertension (OHT)
- Route of Administration: Ophthalmic
- Dosage Form: Ophthalmic Suspension
- Strength: 1%/0.2%
- Dose and Frequency: One drop in affected eye(s) 3 times a day
- How Supplied: [redacted] (b) (4) 8 mL in 10 mL LDPE DROP-TAINER bottle with [redacted] (b) (4) cap
- Storage: Store at 2°C to 25°C (36°F-77°F)
- Container and Closure Systems: Sterile opaque 10 mL white LDPE plastic DROP-TAINER bottles and natural tips with [redacted] (b) (4) polypropylene caps. [redacted] (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The June 4, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Simbrinza, was not derived from any particular concept and does not have any intended meaning. This proprietary name is comprised of a single word that contains components of both established names. Simbrinza contains 5 letters 'brinz' of the first established name, brinzolamide, as well as several letter strings of the second established name, brimonidine, represented by the letters 'bri' or 'im'.

2.2.3 FDA Name Simulation Studies

Thirty-seven practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Most participants in the prescription study correctly interpreted the name Simbrinza. Of the inpatient participants who did not correctly interpret the name, the majority misinterpreted the letter 'z' for the letters 'c', 'i', or 'r' and the first letter 'i' in Simbrinza with the letter 'u'. Many of the verbal participants misinterpreted the 'i' in the suffix 'Sim' with 'y', and the majority of the misinterpretations in the outpatient study was with the letter 'z' in Simbrinza interpreted as the letter 'g'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, March 28, 2012 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Simbrinza. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Simbrinza identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by the [redacted] (b) (4) not identified by DMEPA, and require further evaluation.

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

Look Similar		**Look Similar**		**Look Similar**	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Domeboro	EPD	Simponi	EPD	Symbyax	EPD
Gentamicin	EPD	Simulect	EPD	(b) (4)	Primary SE
(b) (4)	Primary SE	Somatropin	EPD	Tambocor	EPD
Sambucol	SEPD	Somatuline	EPD	Temazepam	EPD
Sanctura	EPD	Sumatriptan	EPD	Temovate E	EPD
Simethicone	EPD	Sustiva	EPD		
Semilente	EPD	SymlinPen	EPD		
Look and Sound Similar		**Look and Sound Similar**		**Look and Sound Similar**	
Albenza	(b) (4)	Singulair	(b) (4)	Symbicort	EPD/ (b) (4)
Avinza	(b) (4)	Spiriva	(b) (4)	Zolinza	(b) (4)
Simvastatin	(b) (4)	Suprenza	EPD/ (b) (4)	Zyprexa	EPD/ (b) (4)
Sound Similar		**Sound Similar**		**Sound Similar**	
Cymbalta	EPD	Semprex-D	EPD	Somavert	EPD/ (b) (4)

Our analysis of the 31 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 31 names will not pose a risk for confusion as described in Appendices D and E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Transplant and Ophthalmology Products via e-mail on June 14, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Transplant and Ophthalmology Products on June 25, 2012, they stated no additional concerns with the proposed proprietary name, Simbrinza; however, they provided feedback on the proposed cap color, which is discussed in Section 3.

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3 DISCUSSION

(b) (4)

The Division stated "The AAO doesn't currently have a cap color designated for this particular drug combination; in the absence of a designated cap color, the cap should be white. The stability studies were all performed with white caps so there should be no problem." The Division will recommend to the Applicant to change the color of the cap to white, a color that does not overlap with the existing cap color coding system for topical ocular medications. We will also address the issue regarding the cap color in our label and labeling review under NDA 204251.

4 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 Townsend, OSE project manager, at 301-796-5413.

4.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 3, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

5 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

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

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

19. Dogpile (www.dogpile.com)

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

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 gathered 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

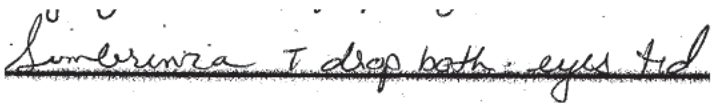
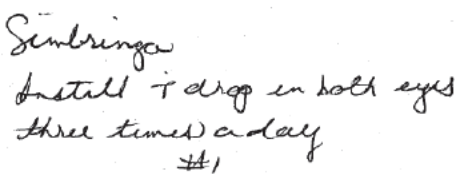
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval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

Letters in Name, Simbrinza	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'S'	5, A, D, G, T, Z	'X', 'C', 'Z'
Lower Case 's'	5, G, g, n	'x', 'c'
Lower Case 'i'	e	'e', 'y'
Lower Case 'm'	n, nn, rn, v, vi, w, wi, onc, z	'n'
Lower Case 'b'	l, h, k	'p', 'v', 'd'
Lower Case 'r'	e, i, l, n, s, v	
Lower Case 'br'	fr, tr	pr
Lower Case 'i'	e	'e', 'y'
Lower Case 'n'	h, m, r, s, u, v, x	'dn', 'gn', 'kn', 'mn', 'pn'
Lower Case 'z'	c, e, g, m, n, q, r, s, v	'c', 's', 'x'
Lower Case 'a'	ce, FL, H, s	Any Vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Simbrinza Study (Conducted on April 9, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Simbrinza Instill 1 drop into both eyes 3 times a day #1 Bottle
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Simbrinza

As of Date 5/30/2012

84 People Received Study

37 People Responded

Study Name: Simbrinza

Total	**11**	**14**	**12**	**37**
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
CYMBRENZA	0	1	0	1
SEMBRENZA	0	1	0	1
SIMBRENZA	0	1	0	1
SIMBRINCA	1	0	0	1
SIMBRINGA	0	0	4	4
SIMBRINGO	0	0	1	1
SIMBRINIA	1	0	0	1
SIMBRINRA	1	0	0	1
SIMBRINZA	5	1	7	13
SUBRINRA	1	0	0	1
SUMBRENZA	1	0	0	1
SUMBRINRA	1	0	0	1
SYMBRENZA	0	5	0	5
SYMBRINZA	0	5	0	5

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described. (n=22)

No.	Proprietary Name	Active Ingredient	Similarity to Simbrinza	Failure preventions
1	Albenza	Albendazole	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
2	Avinza	Morphine Sulfate Beads	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
3	Domeboro	Aluminum Acetate	Look Alike	The pair has sufficient orthographic differences
4	(b) (4)			
5	Sambucol	Black Elderberry Extract	Look Alike	The pair has sufficient orthographic differences
6	Semprex-D	Pseudoephedrine HCl	Sound Like	The pair has sufficient phonetic differences
7	Simethicone	Simethicone	Look Alike	The pair has sufficient orthographic differences
8	Semilente	Promp Beef or Promp Purified Pork Insulin Zinc Suspension	Look Alike	The pair has sufficient orthographic differences. This product is no longer commercially available in the US and no generic equivalents exist. Withdrawn FR effective 9/25/1997 and 8/5/1996, respectively for NDA 017996 and NDA 018382.
9	Simponi	Golimumab	Look Alike	The pair has sufficient orthographic differences
10	Simulect	Basiliximab	Look Alike	The pair has sufficient orthographic differences
11	Simvastatin	Simvastatin	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
12	Singulair	Montelukast Sodium	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
13	Somatuline Depot	Lanreotide Acetate	Look Alike	The pair has sufficient orthographic differences

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

No.	Proprietary Name	Active Ingredient	Similarity to Simbrinza	Failure preventions
14	Somavert	Pegvisomant	Sound Alike	The pair has sufficient phonetic differences
15	Spiriva HandiHaler	Tiotropium Bromide Monohydrate	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
16	Sustiva	Efavirenz	Look Alike	The pair has sufficient orthographic differences
17	Symbyax	Olanzepine/Fluoxetine	Look Alike	The pair has sufficient orthographic differences
18	Tambocor	Flecainide Acetate	Look Alike	The pair has sufficient orthographic differences
19	Temazepam	Temazepam	Look Alike	The pair has sufficient orthographic differences
20	Temovate E	Clobetasol Proprionate Emollient Base	Look Alike	The pair has sufficient orthographic differences
21	Zolinza	Vorinostat	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences
22	Zyprexa	Olanzepine	Look & Sound Alike	The pair has sufficient orthographic and phonetic differences

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. (n=9)

No.	**Proposed name: Simbrinza** **Dosage Form: Ophthalmic Suspension** **Strength: 1%/0.2%** **Usual Dose: One drop in affected eye(s) 3 times a day**	**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	Cymbalta (Duloxetine HCl) Capsules **Strengths:** 20 mg, 30 mg, 60 mg **Usual Dose:** 30 mg to 120 mg by mouth once daily	**Orthographic and Phonetic Similarities:** Both names contain the letter string 'mb' in similar positions of the name, contain letters that may be scripted similarly (t vs. z when done with a cross-stroke) in the 7th position, and end with the letter 'a'. Both names contain 3 syllables and when spoken, the first syllable in each same sound identical (Cymb vs. Simb). **Dose:** Both can be prescribed as "one" if the dosage form was omitted. (One capsule vs. One drop)	**Orthographic and Phonetic Differences:** The first letter in both names appears different when scripted (C vs. S). Also, Cymbalta contains an upstroke 'l' in the 6th position which is not seen with Simbrinza, giving the names a different shape and appearance. When spoken, the second syllable in Cymbalta is distinctly different than the second syllable in Simbrinza (alt vs. rinz). **Differentiating Product Characteristics:** Strength: No strength overlap. Cymbalta is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Cymbalta. Frequency: Once daily vs. 3 times daily

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	Gentamicin (Gentamicin Sulfate) Injection Solution, in Sodium Chloride 0.9% Solution for Injection, Topical Cream, Topical Ointment, Ophthalmic Solution, Ophthalmic Ointment Injection Solution: **Strengths:** 10 mg/mL, 40 mg/mL **Usual Dose:** *Serious Infections*—3 mg/kg/day intravenously or intramuscularly in 3 equal doses every 8 hours. For example, for a patient weighing 75 kg, the dose would be approximately 225 mg/day (75 mg 3 times daily). *Life-Threatening Infections*—Up to 5 mg/kg/day intravenously or intramuscularly in 3 or 4 equal doses. Reduce to 3 mg/kg/day as soon as clinically indicated. For example, for a patient weighing 75 kg, the dose would be approximately 375 mg/day (125 mg 3 times a day or 94 mg 4 times a day).	**Orthographic Similarity:** Both names contain orthographically similar first letters (g vs. S) and contain an upstroke in the 4th position (t vs. b). **Route of Administration:** Both may be given ophthalmically.	**Orthographic Difference:** The suffix 'amicin' in Gentamicin appears longer when scripted than the suffix 'rinza' in Simbrinza (6 letters vs. 5 letters). **Differentiating Product Characteristics:** Strength: No strength overlap. Gentamicin is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Gentamicin. Dosage Form: Gentamicin is available in multiple dosage forms. A dosage form would need to be specified in order to prescribe Gentamicin. Injection Solution or Topical Ointment or Cream or Ophthalmic Solution or Ointment vs. Ophthalmic Suspension

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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
	Children: 2 mg/kg to 2.5 mg/kg intravenously or intramuscularly every 8 hours. For example, for a child weighing 34 kg, the dose would be approximately 68 kg to 85 kg every 8 hours. *Neonates:* 2.5 mg/kg intravenously or intramuscularly every 8 to 24 hours. For example, for a neonate weighing 2 kg, the dose would be approximately 5 mg every 8 to 24 hours. Injection Solution in 0.9% Sodium Chloride: **Strengths:** 0.6 mg/mL, 0.8 mg/mL, 0.9 mg/mL, 1 mg/mL, 1.2 mg/mL, 1.4 mg/mL, 1.6 mg/mL, 2 mg/mL **Usual Dose:** *Serious Infections*— 3 mg/kg/day intravenously or intramuscularly in 3 equal doses every 8 hours. For example, for a patient weighing 75 kg, the dose would be approximately 225 mg/day (75 mg 3 times a day).		

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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
	Life-Threatening Infections—Up to 5 mg/kg/day intravenously or intramuscularly in 3 or 4 equal doses. Reduce to 3 mg/kg/day as soon as clinically indicated. For example, for a patient weighing 75 kg, the dose would be approximately 375 mg/day (125 mg 3 times a day or 94 mg 4 times a day). *Children:* 2 mg/kg to 2.5 mg/kg intravenously or intramuscularly every 8 hours. For example, for a child weighing 34 kg, the dose would be approximately 68 kg to 85 kg every 8 hours. *Neonates:* 2.5 mg/kg intravenously or intramuscularly every 8 to 24 hours. For example, for a neonate weighing 2 kg, the dose would be approximately 5 mg every 8 to 24 hours. Topical Cream/Ointment: **Strength:** 0.1% **Usual Dose:** Apply to the affected skin area 3 to 4 times daily		

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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
	<u>Ophthalmic Solution:</u> **Strength:** 0.3% **Usual Dose:** Instill 1 to 2 drops into the affected eye every 4 hours. For severe infections, instill up to 2 drops every 1 hour <u>Ophthalmic Ointment:</u> **Strength:** 0.3% **Usual Dose:** Apply a small amount of ointment to the affected eye(s) 2 to 3 times daily		
3	Sanctura (Trospium Chloride) Tablet **Strength:** 20 mg **Usual Dose:** 1 tablet (20 mg) by mouth once or twice daily	**Orthographic Similarity:** Both names begin with the letter 'S' and end with the letter 'a'. **Strength:** Both products are available in a single strength. **Dose:** Both can be given as a "one" dose. (One tablet vs. One drop)	**Orthographic Difference:** Sanctura contains a cross-stroke 't' in the 5th position of the name while Simbrinza contains an upstroke 'b' in the 4th position. Also, the suffix 'ura' in Sanctura contains only 3 letters compared to 'rinza' in Simbrinza which contains 5 letters making the name Simbrinza appear longer when scripted.

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	Somatropin (Somatropin Recombinant rhGH) Injection Solution, Powder for Injection **Strengths:** Injection Solution: 5 mg/1.5 mL, 10 mg/1.5 mL, 5 mg/2mL, 10 mg/2mL, 20 mg/2mL, 30 mg/3 mL Powder for Injection: 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, 2 mg, 5 mg, 5.8 mg, 6 mg, 8.8 mg, 10 mg, 12 mg, 24 mg **Usual Dose:** Dosage is varied based on the Somatropin product given. Also, dosage must be adjusted for the individual patient. Genotropin & Omnitrope- 0.04 mg/kg/week to 0.08 mg/kg/week given in 7 divided daily subcutaneous injections or 0.15 mg/day to 0.3 mg/day without consideration to body weight. For example, for a patient weighing 75 kg, the dose would be approximately 0.43 mg to 0.86 mg per day.	**Orthographic Similarity:** Both names begin with the letter 'S', contain the letter 'm' in the 3rd position and a potential downstroke in the 8th position of their names.	**Orthographic Difference:** Somatropin contains a rounded vowel 'o' in the 2nd position while Simbrinza contains a more narrow vowel 'i'. Somatropin also contains an extra vowel 'a' in the 4th position of the name which is not seen in Simbrinza giving the prefix in the name Somatropin a longer appearance when scripted. Also, Somatropin contains a cross-stroke 't' in the 5th position while Simbrinza contains an upstroke 'b' in the 4th position of the name. **Differentiating Product Characteristics:** Strength: No strength overlap. Somatropin is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Somatropin. Unit of Measure: Inject XX mg or XX mL vs. One drop A specific brand of Somatropin would need to be specified on a prescription since Somatropin is available in multiple products with doses that vary based on the product chosen.

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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
	Humatrope & HumatroPen-0.006 mg/kg/day to 0.125 mg/kg/day subcutaneously daily. For example, for a patient weighing 75 kg, the dose would be approximately 0.45 mg to 9.375 mg daily. Norditropin-0.004 mg/kg/day to 0.016 mg/kg/day subcutaneously daily. For example, for a patient weighing 75 kg, the dose would be approximately 0.3 mg to 1.2 mg daily. Nutropin & Nutropin AQ-0.006 mg/kg/day to 0.025 mg/kg/day subcutaneously daily. For example, for a patient weighing 75 kg, the dose would be approximately 0.45 mg to 1.875 mg daily. Saizen-0.005 mg/kg/day to 0.01 mg/kg/day subcutaneously daily. For example, for a patient weighing 75 kg, the dose would be approximately 0.375 mg to 0.75 mg daily. Zorbtive-0.1 mg/kg/day to 8 mg/day subcutaneously daily.		

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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
	For example, for a patient weighing 75 kg, the dose would be approximately 7.5 mg to 600 mg daily. Serostim-0.1 mg/kg/day to 6 mg/kg/day subcutaneously daily. For example, for a patient weighing 75 kg, the dose would be approximately 7.5 mg to 450 mg daily.		

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	Sumatriptan (Sumatriptan Succinate) Injection Solution, Tablets, Nasal Solution Injection Solution: **Strengths:** 4 mg/0.5 mL, 6 mg/0.5mL **Usual Dose:** 6 mg injected subcutaneously, may repeat once after 1 hour, not to exceed 12 mg in 24 hours Tablets: **Strengths:** 25 mg, 50 mg, 100 mg **Usual Dose:** 25 mg to 200 mg by mouth daily Nasal Solution: **Strengths:** 5 mg/Actuation, 20 mg/Actuation **Usual Dose:** 5 mg to 20 mg into 1 nostril, may be repeated once after 2 hours, not to exceed 40 mg daily	**Orthographic Similarity:** Both names begin with the letter 'S', contain the letter 'm' in the 3rd position and a potential downstroke in the 8th position of their names. **Dose:** Both can be prescribed as "one" if the dosage form is omitted. (One injection, One tablet, One inhalation vs. One drop)	**Orthographic Difference:** Sumatriptan contains a cross-stroke 't' in the 5th and 9th position of the name while Simbrinza contains an upstroke 'b' in the 4th position. Sumatriptan contains 11 letters vs. 9 letters in Simbrinza giving the name a longer appearance than Simbrinza. **Differentiating Product Characteristics:** Strength: No strength overlap. Sumatriptan is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Somatropin. Dosage Form: Sumatriptan is available in multiple dosage forms. A dosage form would need to be specified in order to prescribe Sumatriptan. Injection Solution or Tablets or Nasal Solution vs. Ophthalmic Suspension

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	Suprenza (Phentermine HCl) Tablets **Strengths:** 15 mg, 30 mg **Usual Dose:** 1 tablet by mouth in the morning	**Orthographic and Phonetic Similarities:** Both names begin with the letter 'S' and end with the letter string 'nza'. Both names contain 3 syllables and when spoken last 2 syllables may sound similar (prenza vs. brinza). **Dose:** Both can be given as a "one" dose. (One tablet vs. One drop)	**Orthographic and Phonetic Differences:** Suprenza contains a downstroke 'p' in the 3rd position of the name while Simbrinza contains an upstroke 'b' in the 4th position of the name giving the names a different shape and appearance. When spoken, the first syllable of this name pair sound distinctly different (Su vs. Sim). **Differentiating Product Characteristics:** Strength: No strength overlap. Suprenza is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Suprenza.
7	Symbicort (Budesonide/Formoterol Fumerate) Inhalation Aerosol **Strengths:** 80 mcg/4.5 mcg, 160 mcg/4.5 mcg **Usual Dose:** 2 inhalations by mouth twice daily	**Orthographic and Phonetic Similarities:** Both names contain 9 letters, begin with the letter 'S' and contain a similar letter string 'mb' in the infix of the name. Both names contain 3 syllables and when spoken, the first syllable sounds identical (Sym vs. Sim).	**Orthographic and Phonetic Differences:** Symbicort contains a downstroke 'y' in the 2nd position of the name and a cross-stroke 't' in the last position which is not seen in Simbrinza giving the names a different shape and appearance. When spoken, the 2nd and 3rd syllables in the name pair sound distinctly different (bicort vs. brinza). **Differentiating Product Characteristics:** Strength: No strength overlap. Symbicort is available in multiple strengths vs. a single strength for Simbrinza. When prescribed a strength would need to be specified for Symbicort. Dose: Two Inhalations or puffs vs. One drop

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	SymlinPen 60 and SymlinPen 120 (Pramlintide Acetate) Injection Solution **Strength:** 1000 mcg/mL **Usual Dose:** Type 1 Diabetes Mellitus: 15 mcg to 60 mcg subcutaneously prior to each meal Type 2 Diabetes Mellitus: 60 mcg to 120 mg subcutaneously prior to each meal SymlinPen 60 is for doses of 15 mcg, 30 mcg, 45 mcg, and 60 mcg SymlinPen 120 is for doses of 60 mcg and 120 mcg	**Orthographic Similarity:** Both names contain 9 letters, begin with the letter 'S' and contain a similar letter string (ml vs. mb) in the infix of the name. **Strength:** Both products are available in a single strength. **Frequency of Administration:** Both products can be dosed 3 times a day.	**Orthographic Difference:** SymlinPen contains a downstroke 'y' in the 2nd position of the name and either an upstroke or downstroke 'P' or 'p', depending on how it is scripted, in the 7th position of the name which is not seen in Simbrinza giving the names a different shape and appearance. **Differentiating Product Characteristics:** Dose: No dose overlap. Inject XX mcg vs. One drop Modifier: A modifier would need to be specified for SymlinPen (60 or 120) in order to dispense the correct product for the dose prescribed.

No.	Proposed name: Simbrinza Dosage Form: Ophthalmic Suspension Strength: 1%/0.2% Usual Dose: One drop in affected eye(s) 3 times a day	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	(b) (4)		

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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08/08/2012

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