

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203414Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: November 21, 2012

Reviewer(s): Reasol S. Agustin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength(s): Kazano (Alogliptin and Metformin) Tablets,
12.5 mg/500 mg and 12.5 mg/1000 mg

Application Type/Number: NDA 203414

Applicant/Sponsor: Takeda Global Research and Development

OSE RCM #: 2012-2400

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Kazano, 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, Kazano, acceptable in OSE Review #2012-1024 dated July 19, 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 #2012-1024. 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 three new names (Kuvan, Rayos, and Ximino), thought to look similar to Kazano and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Kazano and lead to medication errors. This analysis determined that the name similarity between Kazano and the identified names 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 November 16, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on October 25, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Office of Metabolism and Endocrinology Products (DMEP) 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 Margarita Tossa, OSE project manager, at 301-796-4053.

4 REFERENCES

1. OSE Review #2012-1024 dated July 19, 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: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

<p>Proposed name: Kazano (Alogliptin and Metformin) Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>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</p>
<p>Kuvan (Sapropterin Dihydrochloride) Dosage Form and Strength: Oral tablet- soluble: 100 mg Usual dose: 10 mg/kg/day once daily Dosing range based on adult body weight 10 kg to greater than 100 kg = 100 mg to greater than 1000 mg) Average dose is based on a 25 kg child = 250 mg once daily</p>	<p>Orthographic similarity: Both names begin with the letter ‘K’ and the letter strings ‘azan’ and ‘uvan’ appear orthographically similar when scripted, if the letter ‘z’ is scripted with a downstroke. Dosage form and route of administration: Both are available as oral dosage forms. Strength: Although Kazano is a combination product, it is more likely that product’s fixed strength (12.5 mg) will be omitted during prescribing than its variable strength (i.e. 500 mg and 1000 mg). Thus, the variable strength can be written and considered a complete prescription. There is numerical overlap between the strengths (<i>i.e. 100 mg vs. 1000 mg</i>) Dose: There is numerical overlap between the doses (<i>500 mg and 1000 mg</i>)</p>	<p>Orthographic difference: Kazano contains an additional letter ‘o’ at the end of the name which is absent in Kuvan, making Kazano appear longer than Kuvan when scripted.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Rayos (Prednisone)</p> <p>Dosage Form and Strength: Oral tablet- delayed release: 1 mg, 2 mg, and 5 mg</p> <p>Usual dose: Initial dose: 5 mg to 60 mg (1 to 12 tablets) once daily</p>	<p>Orthographic similarity: The beginning letter strings ‘Kaza’ and ‘Rayo’ appear orthographically similar when scripted, if the letter ‘z’ is scripted with a downstroke.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: The ending letter strings ‘no’ and ‘os’ appear orthographically different when scripted.</p> <p>Strength: Both Kazano and Rayos are available in multiple strengths and will require strength for a complete prescription. There is no numerical overlap between the strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>												
<p>Ximino (Minocycline Hydrochloride)</p> <p>Dosage Form and Strength: Oral capsule- extended release: 45 mg, 67.5 mg, 90 mg, 112.5 mg, 135 mg</p> <p>Usual dose: 1 mg/kg/day once daily for 12 weeks.</p> <table border="1" data-bbox="123 1108 561 1505"> <thead> <tr> <th>Patient's weight (Kg)</th> <th>Capsule Strength (mg)</th> </tr> </thead> <tbody> <tr> <td>45 kg to 55 kg</td> <td>45 mg</td> </tr> <tr> <td>56 kg to 74 kg</td> <td>67.5 mg</td> </tr> <tr> <td>75 kg to 96 kg</td> <td>90 mg</td> </tr> <tr> <td>97 kg to 125 kg</td> <td>112.5 mg</td> </tr> <tr> <td>126 kg to 136 kg</td> <td>135 mg</td> </tr> </tbody> </table>	Patient's weight (Kg)	Capsule Strength (mg)	45 kg to 55 kg	45 mg	56 kg to 74 kg	67.5 mg	75 kg to 96 kg	90 mg	97 kg to 125 kg	112.5 mg	126 kg to 136 kg	135 mg	<p>Orthographic similarity: The beginning letter 'K' and 'X' appear orthographically similar when scripted. In addition, both names end with the letter strings 'no'</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: The letter strings 'aza' and 'imi' appear orthographically different when scripted.</p> <p>Strength: Both Kazano and Ximino are available in multiple strengths and will require strength for a complete prescription. There is no numerical overlap between the strengths.</p>
Patient's weight (Kg)	Capsule Strength (mg)													
45 kg to 55 kg	45 mg													
56 kg to 74 kg	67.5 mg													
75 kg to 96 kg	90 mg													
97 kg to 125 kg	112.5 mg													
126 kg to 136 kg	135 mg													

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**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: July 19, 2012

Reviewer(s): Reasol S. Agustin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

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Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Kazano (Alogliptin and Metformin) Tablets,
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Application Type/Number: NDA 203414

Applicant/Sponsor: Takeda Global Research and Development

OSE RCM #: 2012-1024

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant submitted a request for an assessment of the proposed proprietary name, Kazano for Alogliptin and Metformin tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg, NDA 203414 on April 24, 2012. The name Kazano is the second proposed name for this product. The first proposed proprietary name (b) (4) submitted to NDA 203414 on November 22, 2011 was withdrawn by the applicant on January 12, 2012 because of agency's concern regarding the proposed proprietary names. The second proposed proprietary name (b) (4) submitted on January 18, 2012 was found unacceptable by DMEPA in OSE Review #2012-216, dated April 13, 2012 (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the April 24, 2012 proprietary name submission.

- Active Ingredient: Alogliptin and Metformin
- Indication of Use: Adjunct to diet and exercise to improve glycemic control in adult patients with Type 2 Diabetes Mellitus
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 12.5 mg/500 mg and 12.5 mg/1000 mg
- Dose and Frequency: One tablet twice daily with food; maximum dose of 25 mg per day of Alogliptin and 2000 mg per day of Metformin
- How Supplied: 60 count, 180 count, and 500 count bottles
- Storage: Store at 77° F, excursions permitted to 59° F to 86° F.
- Container and Closure Systems:
 - Bottles: HDPE bottle (b) (4)
 - Blister: (b) (4)

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2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) 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 May 10, 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, Kazano, was not derived from any one particular concept and has no 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.

2.2.3 FDA Name Simulation Studies

Twenty-six practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Three of the 10 inpatient participants responded correctly and the most common misinterpretation occurred with 3 participants misinterpreting the letter 'n' for 'rr' in 'KazaNo.' Three of the 8 voice participants responded correctly and the most common misinterpretation occurred with 3 participants misinterpreting the letter 'K' for 'C' in 'Kazano.' Two out of 8 outpatient participants responded correctly and the most common misinterpretation occurred with 4 participants misinterpreting the letter 'v' for 'u' and 3 participants misinterpreting 'n' for 'm' in 'KazaNo.' See Appendix C for the complete listing of interpretation from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, May 3, 2012 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) 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, Kazano. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Kazano

identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines,

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Kynamro ^{***}	FDA	(b) (4) ^{***}	FDA	Lorzone	FDA
Kionex	FDA	(b) (4) ^{***}	FDA	Razadyne	FDA
Kafocin	FDA	Ranexa	FDA	Prazosin	FDA
Rezipas	FDA	Kavatrol	FDA	Rozerem	FDA
Rezulin	FDA	Renese Renese-R	FDA	Xanax Xanax XR	FDA
Konesta	FDA	Rezira	FDA	Rogaine	FDA
Kouso	FDA	Regaine Forte	FDA	Revive	FDA
Rogenic	FDA	Revonto	FDA	(b) (4) ^{***}	FDA
(b) (4) ^{***}	FDA	Rezine	FDA	Renova	FDA
(b) (4) ^{***}	FDA	Kinevac	FDA	Xerese	FDA
(b) (4) ^{***}	FDA	Rowasa	FDA	Revatio	FDA
Xenazine	FDA	Renvela	FDA	Remeron	FDA
Remeven	FDA	Kariva	FDA		
Look and Sound Similar					
Canasa	FDA				

^{***} This is proprietary and confidential information that should not be released to the public

Our analysis of the 39 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the 39 total number of names will pose a risk for confusion as described in Appendix D and E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on June 5, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Division of Metabolism and Endocrinology Products (DMEP) on June 18, 2012, they stated no additional comments with the proposed proprietary name, Kazano.

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 Margarita Tossa, OSE project manager, at 301-796-4053.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Kazano, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your April 24, 2012 submission are altered, DMEPA rescinds this finding and 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. *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.

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

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

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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> • 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 	

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

Look-alike			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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

“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.

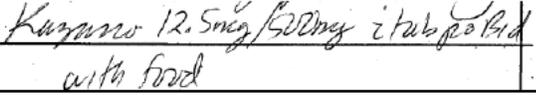
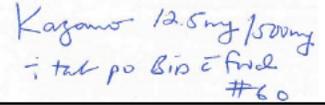
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, Kazano	Scripted may appear as	Spoken may be interpreted as
‘K’ ‘k’	R, X, x, h, la	C, Qu, Que, Q
Lowercase ‘a’	el, ci, cl, d, o, u, e	Any vowel
lowercase ‘z’	c, e, g, n, m, q, r, s, v	c, s, x
lowercase ‘a’	el, ci, cl, d, o, u, e	Any vowel
lowercase ‘n’	m, u, r, h, s	dn, gn, mn, pn
lowercase ‘o’	a, c, e, u	Oh

Appendix C: Prescription Simulation Samples and Results

Figure 1. Kazano Study (Conducted on May 11, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p>	<p>Kazano 12.5 mg/500 mg Take 1 tablet orally twice daily with food</p>
<p><u>Outpatient Prescription:</u> </p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study

26 People Responded

Total	10	8	8	26
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CAZANO	0	3	0	3
CAZONO 12.5MG/1000MG	0	1	0	1
COZANO	0	1	0	1
KAGAMO	0	0	1	1
KAZAMO	0	0	4	4
KAZAMO 12.5 MG/500 MG	0	0	1	1
KAZANO	3	3	2	8
KAZARRO	3	0	0	3
KAZRINO	1	0	0	1
KAZUNO	1	0	0	1
KAZZARO	1	0	0	1
KUZUNO	1	0	0	1

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

Proprietary Name	Active Ingredient	Similarity to Kazano	Failure preventions
Kynamro***	(Mipomersen Sodium)	Orthographic	The pair have sufficient orthographic differences
Kionex	Sodium Polystyrene Sulfonate	Orthographic	The pair have sufficient orthographic differences
Kafocin	Cephaloglycin	Orthographic	Name identified in FDA database. Unable to find product characteristics in commonly used drug databases. Product Withdrawn, FR Effective 5/29/2002
Rezipas	Aminosalicylic Acid Resin Complex	Orthographic	Name identified in FDA database. Unable to find product characteristics in commonly used drug databases. Product Withdrawn, FR Effective 9/13/2000
Rezulin	Troglitazone	Orthographic	Voluntary withdrawal by Applicant due to concern about severe liver toxicity, Withdrawn FR Effective 1/10/2003
Konesta	Trichloroacetic Acid	Orthographic	Proprietary name for a raw ingredient used in chemical manufacturing and compounding, also used experimentally for treatment of warts, however would not be prescribed.
Koussou	Vitamin Supplement	Orthographic	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
Rogenic	Cyanocobalamin/Iron/Liver	Orthographic	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.

(b) (4)



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.

<p>Proposed name: Kazano (Alogliptin and Metformin) Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>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</p>
<p>Ranexa (Ranolazine) Dosage Form and Strength: Oral tablet 12-hour extended release: 500 mg and 1000 mg Usual dose: One tablet (500 to 1000 mg) by mouth twice daily</p>	<p>Orthographic similarity: ‘Kazano’ and ‘Ranexa’ appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped. Strength: Both Kazano and Ranexa are available in multiple strengths. Although Kazano is a combination product, the alogliptin strength is constant thus may be considered a complete prescription when written with only the metformin strength (500 mg and 1000 mg). There is numerical overlap between the two strengths during prescription writing (<i>i.e. 500 mg and 1000 mg</i>) Dosage form and route of administration: Both are oral dosage forms Frequency: Both are prescribed twice daily</p>	<p>Orthographic difference: The ending letter string ‘no’ and ‘xa’ appear orthographically different when scripted.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Canasa (Mesalamine)</p> <p>Dosage Form and Strength: 1000 mg rectal suppository</p> <p>Usual dose: Insert one suppository in rectum daily at bedtime</p>	<p>Orthographic similarities: The letter strings ‘azano’ and ‘anasa’ appear orthographically similar when scripted.</p> <p>Phonetic similarity: Both names contain three syllables and the first syllable ‘Kah’ sounds phonetically similar when spoken.</p> <p>Strength: Although Kazano is a combination product, it is more likely that product’s fixed strength (12.5 mg) will be omitted during prescribing than its variable strength (i.e. 500 mg and 1000 mg). Thus, the variable strength can be written and considered a complete prescription. There is numerical overlap between the strengths (<i>i.e. 1000 mg</i>)</p>	<p>Orthographic similarities: The letter ‘K’ and ‘C’ appear orthographically different when scripted.</p> <p>Phonetic difference: The second syllables ‘zahn’ and ‘na’ and third syllables ‘oh’ and ‘sa’ sound phonetically different when spoken</p> <p>Dose: Take one tablet vs. Insert 1 rectally</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Kariva (Ethinyl Estradiol and Desogestrel)</p> <p>Dosage Form and Strength: Oral tablets: 0.02 mg/0.15 mg</p> <p>Usual dose: One tablet by mouth once daily</p>	<p>Orthographic similarities: Both names begin with the letter string ‘Ka.’ The letter ‘z’ and ‘r’ and the ending letter strings ‘no’ and ‘va’ appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic similarities: The fourth letter ‘a’ in Kazano and ‘i’ in Kariva appear orthographically different when scripted.</p> <p>Strength: Single vs. multiple. Kariva is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Lorzone (Chlorzoxazone)</p> <p>Dosage Form and Strength: Oral tablet: 375 mg, 500 mg, 750 mg</p> <p>Usual dose: One tablet (250 to 500 mg) 3 or 4 times daily.</p>	<p>Orthographic similarity: The ending letter strings ‘zano’ and ‘zone’ appear orthographically similar when scripted.</p> <p>Strength: Both Kazano and Lorzone are available in multiple strengths therefore a strength is required for a complete prescription. Although Kazano is a combination product, the variable strength (500 mg and 1000 mg) can be written and considered a complete prescription. There is numerical overlap between the strengths (<i>i.e. 500 mg</i>)</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic difference: The beginning letter strings ‘K’ and ‘L’ and the letter strings ‘a’ and ‘or’ appear orthographically different when scripted.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Renese (Polythiazide)</p> <p>Dosage Form and Strength: Oral tablets: 1 mg, 2 mg, 4 mg</p> <p>Usual dose: 1 to 4 tablets by mouth once daily</p> <p>Renese-R (Polythiazide and Reserpine)</p> <p>Dosage Form and Strength: Oral tablets: 2 mg/0.25 mg</p> <p>Usual dose: One-half to 2 tablets by mouth once daily</p>	<p>Orthographic similarity: 'Kaz' and 'Ren' appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic difference: The letter strings 'ano' and 'ese' appear orthographically different when scripted.</p> <p>Strength: Both Kazano and Renese are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap between the two strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Rezira (Hydrocodone and Pseudoephedrine)</p> <p>Dosage Form and Strength: Oral solution: 5 mg/60 mg per 5 mL</p> <p>Usual dose: 5 mL by mouth every 4 to 6 hours as needed, max 20 mL/24 hours</p>	<p>Orthographic similarity: The letter strings ‘Kaz’ and ‘Rez’ and the ending letter strings ‘no’ and ‘ra’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic similarity: The fourth letter ‘a’ in Kazano and ‘i’ in Rezira appear orthographically different when scripted.</p> <p>Strength: Single vs. multiple. Rezira is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p> <p>Dose: One tablet vs. 5 mL to 20 mL</p> <p>Frequency: Kazano is prescribed twice daily vs. Rezira is prescribed every 4 to 6 hours as needed.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xanax (Alprazolam)</p> <p>Xanax XR (Alprazolam Extended-Release)</p> <p>Dosage Form and Strength: Oral tablet: 0.25 mg, 0.5 mg, 1 mg, 2 mg Extended release oral tablet: 0.5 mg, 1 mg, 2 mg, 3 mg</p> <p>Usual dose: Immediate release: One tablet (0.25 to 0.5 mg) by mouth three times daily; Maintenance dose range: 3 to 6 mg/day Extended-release: One tablet (0.5 to 1 mg) by mouth once daily; Maintenance dose range: 3 to 6 mg/day</p>	<p>Orthographic similarity: The letter strings ‘Kaza’ and ‘Xana’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic difference: The ending letter strings ‘no’ and ‘x’ appears orthographically different when scripted.</p> <p>Strength: Both Kazano and Xanax are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap between the two strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Razadyne (Galantamine HBr)</p> <p>Dosage Form and Strength: Immediate release (IR) oral tablet: 4 mg, 8 mg, 12 mg Oral solution: 4 mg/mL Extended release (ER) capsule: 8 mg, 16 mg, 24 mg</p> <p>Usual dose: IR: 4 to 12 mg by mouth twice daily ER: 8 to 24 mg once daily</p>	<p>Orthographic similarity: The letter ‘K’ and ‘R’ appear orthographically similar when scripted. Also, both names contain the letter string ‘aza’ in the same position.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic difference: Razadyne (8 letters) appear orthographically longer than Kazano (6 letters) when scripted. In addition, Razadyne contains an upstroke ‘d’ in the fifth position and a downstroke ‘y’ in the sixth position which is absent in Kazano, giving the names different shapes.</p> <p>Strength: Both Kazano and Razadyne are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap in strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Prazosin (Prazosin)</p> <p>Dosage Form and Strength: Oral capsule: 1 mg, 2 mg, and 5 mg</p> <p>Usual dose: Initial: One tablet (1 mg) by mouth 2 or 3 times per day; maintenance: 6 to 15 mg daily in divided doses</p>	<p>Orthographic similarity: The letter strings ‘azan’ and ‘azos’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic difference: Prazosin (8 letters) appear orthographically longer than Kazano (6 letters) when scripted. In addition, the ending letter strings ‘o’ and ‘sin’ appear orthographically different when scripted.</p> <p>Strength: Both Kazano and Prazosin are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap in strengths</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Kavatrol (Kava Kava)</p> <p>Dosage Form and Strength: Oral capsule: 500 mg</p> <p>Usual dose: One capsule by mouth within 30 to 60 minutes of bedtime as needed to promote sleep</p>	<p>Orthographic similarity: Both names begin with the letter string 'Ka' and the letter strings 'za' and 'va' appear orthographically similar when scripted.</p> <p>Strength: Both Kazano and Kavatrol are available in multiple strengths therefore a strength is required for a complete prescription. Although Kazano is a combination product, the variable strength (500 mg and 1000 mg) can be written and considered a complete prescription. There is numerical overlap between the strengths. (<i>i.e.</i> 500 mg)</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic difference: Kavatrol (8 letters) appear orthographically longer than Kazano (6 letters) when scripted. In addition, Kavatrol contains a cross stroke 't' in the fifth position and an upstroke 'l' in the last position which is absent in Kazano, giving the names different shapes. In addition, the ending letter strings 'no' and 'trol' appear orthographically different when scripted.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Regaine Forte (Minoxidil)</p> <p>Dosage Form and Strength: Topical Solution: 5%</p> <p>Usual dose: 5%: Apply 1 mL twice daily directly onto the scalp in the area of hair thinning/loss, spreading the liquid evenly over the hair loss area. Alert patients that using more or more often will not improve results</p>	<p>Orthographic similarity: The letter strings 'Kaza' and 'Rega' appear orthographically similar when scripted.</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Strength: Single vs. multiple. Regaine is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths. There is no numerical overlap in strengths and the strength units also differ (<i>i.e.</i> 12.5 mg/500 mg and 12.5/1000 mg vs. 5%)</p> <p>Dose: One tablet vs. Apply 1 mL</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Rogaine (Minoxidil)</p> <p>Dosage Form and Strength: Topical Solution: 2% and 5% Foam: 5%</p> <p>Usual dose: 2%: Apply 1 mL to the total affected areas of the scalp twice daily, once in the morning and at night. 5%: Apply 1 mL twice daily directly onto the scalp in the area of hair thinning/loss, spreading the liquid evenly over the hair loss area. Foam 5%: Apply half a capful twice daily to the scalp in the hair loss area</p>	<p>Orthographic similarity: The letter strings ‘Kaza’ and ‘Roga’ appear orthographically similar when scripted.</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Strength: Both Kazano and Rogaine are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap in strengths and the strength units also differ (<i>i.e.</i> 12.5 mg/500 mg and 12.5/1000 mg vs. 2% or 5%)</p> <p>Dose: Take one tablet vs. Apply 1 mL or half a capful</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Revive (Caffeine)</p> <p>Dosage Form and Strength: Oral tablet: 200 mg</p> <p>Usual dose: One tablet (100 to 200 mg) by mouth not more often than every 3 to 4 hours, as needed.</p>	<p>Orthographic similarity: The letter strings ‘Kaz’ and ‘Rev’ appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic similarity: The ending letter strings ‘ano’ and ‘ive’ appear orthographically different when scripted.</p> <p>Strength: Single vs. multiple. Revive is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>
<p>Revonto (Dantrolene Sodium)</p> <p>Dosage Form and Strength: Intravenous solution, reconstituted: 20 mg</p> <p>Usual dose: 25 to 100 mg up to 3 times a day</p>	<p>Orthographic similarity: The letter strings ‘Kazan’ and ‘Revon’ appear orthographically similar when scripted.</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic difference: Revonto contains a cross stroke ‘t’ in the fifth position which is absent in Kazano giving the names different shapes.</p> <p>Strength: Single vs. multiple. Revonto is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Rezine (Hydroxyzine HCl)</p> <p>Dosage Form and Strength: Oral tablet: 10 mg, 25 mg, and 50 mg Oral solution and syrup: 10 mg/5 mL Intramuscular solution: 25 mg/mL and 50 mg/mL</p> <p>Usual dose: Anxiety/tension: 50 to 100 mg 4 times daily Pruritis: 25 mg 3 or 4 times daily Sedation: 50 to 100 mg as premedication or following general anesthesia</p>	<p>Orthographic similarity: The letter strings ‘Kaz’ and ‘Rez’ appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic difference: The ending letter strings ‘ano’ and ‘ine’ appear orthographically different when scripted.</p> <p>Strength: Both Kazano and Rezine are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap in strengths.</p> <p>Dosage form and route of administration: Kazano is available as an oral dosage form vs. Rezine is available as an oral or an injection solution therefore the dosage form or route of administration is required in order to be considered a complete prescription.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Kinevac (Sincalide)</p> <p>Dosage Form and Strength: Powder for injection: 5 mcg</p> <p>Usual dose: Gallbladder Contraction Stimulation and Pancreatic Secretion Testing: Intravenous: 0.02 mcg/kg (1.44 mcg) over 30 to 60 seconds. Intramuscular: 0.1 mcg/kg (7.2 mcg) over 30 to 60 seconds. Average dose is based on a 72 kg adult</p>	<p>Orthographic similarities: Both names begin the letter K and the letter strings ‘zano’ and ‘neva’ appear orthographically similar when scripted.</p>	<p>Orthographic difference: The second letter ‘a’ in Kazano vs. ‘i’ in Kinevac appear orthographically different when scripted. In addition, Kinevac contains an addition letter ‘c’ which is absent in Kazano which helps further differentiate the two names.</p> <p>Strength: Single vs. multiple. Kinevac is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p> <p>Dosage form and route of administration: Kazano is tablet given orally vs. Kinevac is a powder for injection given intravenously or intramuscularly.</p> <p>Frequency: Kazano is prescribed twice daily vs. Kinevac is prescribed once.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Renova (Tretinoin cream)</p> <p>Dosage Form and Strength: Topical cream: 0.02% and 0.05%</p> <p>Usual dose: Apply a pea sized amount to cover the entire affected area once daily before bedtime for 24 to 48 weeks.</p>	<p>Orthographic similarities: 'Kazano' and 'Renova' appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p>	<p>Strength: Both Kazano and Renova are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap in strengths and the strength units also differ (<i>i.e.</i> 12.5 mg/500 mg and 12.5/1000 mg vs. 0.02% or 0.05%)</p> <p>Dose: Take one tablet vs. Apply pea- sized amount</p>

(b) (4)

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xerese (Acyclovir and Hydrocortisone cream)</p> <p>Dosage Form and Strength: Topical cream: Single strength</p> <p>Usual dose: Apply topically to orofacial area 5 times per day for 5 days as early as possible after the first signs and symptoms of herpes labialis occur.</p>	<p>Orthographic similarities: ‘Kazano’ and ‘Xerese’ may appear orthographically similar when scripted. In addition, both names contain the same number of letters and are similarly shaped.</p>	<p>Orthographic similarity: The ending letter strings ‘ano’ and ‘ese’ appear orthographically different when scripted.</p> <p>Strength: Single vs. multiple. Xerese is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p> <p>Frequency: Kazano is prescribed twice daily vs. Xerese is prescribed five times daily</p> <p>Dose: Take one tablet vs. Apply topically</p>
<p>Rowasa (Mesalamine Rectal)</p> <p>Dosage Form and Strength: Rectal enema suspension: 4 g/60 mL</p> <p>Usual dose: 4 grams as a rectal enema retained for approximately 8 hours if possible each night, use for 3 to 6 weeks or until remission is achieved</p>	<p>Orthographic similarities: The letter strings ‘Ka’ and ‘Ro’ and the ending letter strings ‘ano’ and ‘asa’ appear orthographically similar when scripted.</p>	<p>Orthographic similarities: The letter ‘z’ and ‘w’ appear orthographically different when scripted.</p> <p>Strength: Single vs. multiple. Rowasa is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Revatio (Sildenafil)</p> <p>Dosage Form and Strength: Oral tablet: 20 mg Injection solution: 10 mg/12.5 mL</p> <p>Usual dose: Take one tablet (20 mg) by mouth three times per day or Inject 10 mg intravenously three times daily (Injectable sildenafil is intended for the continued treatment of patients with PAH who are currently prescribed oral sildenafil but may be temporarily unable to tolerate oral medication.)</p>	<p>Orthographic similarities: The letter strings ‘Kaza’ and ‘Reva’ appear orthographically similar when scripted.</p>	<p>Orthographic Differences: Revatio contains an upstroke in the sixth position which is absent in Kazano giving the names different shapes.</p> <p>Dose: Although this pair may contain overlapping doses with the 12.5 mg and 12.5 mL, it is more likely that the combination product’s fixed strength (12.5 mg) will be omitted during prescribing than its variable strength (<i>i.e. 12.5/500 mg and 12.5 mg/1000 mg vs. 12.5 mL</i>).</p> <p>Dosage form and route of administration: Kazano is available as oral dosage form vs. Revatio is available in either oral or injectable solution which needs to be specified for a complete prescription.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xenazine (Tetrabenzaine)</p> <p>Dosage Form and Strength: Oral tablets: 12.5 mg and 25 mg</p> <p>Usual dose: Begin with 12.5 mg by mouth every morning, and then increase to 12.5 mg by mouth twice daily.</p> <p>The dose may be increased by 12.5 mg each week if needed. If a patient appears to need greater than 50 mg per day, they should be genotyped for CYP 2D6 expression. For those patients who are intermediate or extensive metabolizers of CYP 2D6 doses of 37.5 to 100 mg per day in three divided doses may be required.</p>	<p>Orthographic similarities: The letter strings ‘Kaza’ and ‘Xena’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Orthographic Differences: Kazano (6 letters) appears orthographically shorter than Xenazine (8 letters) when scripted.</p> <p>Strength: Both Kazano and Xenazine are available in multiple strengths therefore a strength is required for a complete prescription. Although this pair contain an overlapping strength with the 12.5 mg, it is more likely that the combination product’s fixed strength (12.5 mg) will be omitted during prescribing than its variable strength.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Renvela (Sevelamer)</p> <p>Dosage Form and Strength: Oral tablet: 800 mg tablet Powder for suspension: 0.8 gm and 2.4 gm</p> <p>Usual dose: 800 to 1600 mg by mouth three times daily with meals to a maximum dose of 14 grams per day depending on phosphate levels</p>	<p>Orthographic similarities: The letter strings ‘Kaz’ and ‘Ren’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Orthographic Differences: Renvela contains an upstroke ‘l’ in the sixth position which is absent in Kazano giving the names different shapes.</p> <p>Strength: Both Kazano and Renvela are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap between the two strengths.</p>
<p>Remeron (Mirtazapine)</p> <p>Dosage Form and Strength: Oral tablet: 15 mg, 30 mg, and 45 mg</p> <p>Usual dose: 15 mg by mouth nightly; titrate up to 15 to 45 mg per day with dose increases made no more frequently than every 1 to 2 weeks.</p>	<p>Orthographic similarities: The letter strings ‘Kazano’ and ‘Remero’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Strength: Both Kazano and Remeron are available in multiple strengths therefore a strength is required for a complete prescription. There is no numerical overlap between the two strengths.</p>

<p>Proposed name: Kazano (Alogliptin and Metformin)</p> <p>Dosage Form and Strength: Oral Tablet: 12.5 mg/500 mg and 12.5 mg/1000 mg</p> <p>Usual Dose: One tablet twice daily with food</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Remeven (Urea)</p> <p>Dosage Form and Strength: 50% topical cream</p> <p>Usual dose: Apply topically to affected areas 1 to 3 times per day</p>	<p>Orthographic similarities: The letter strings ‘Kaza’ and ‘Reme’ appear orthographically similar when scripted.</p> <p>Frequency: Both can be prescribed twice daily</p>	<p>Strength: Single vs. multiple. Remeven is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>
<p>Rozerem (Ramelteon)</p> <p>Dosage Form and Strength: Oral tablet: 8 mg</p> <p>Usual dose: One tablet by mouth within 30 minutes of bedtime</p>	<p>Orthographic similarities: The letter strings ‘Kazano’ and ‘Rozere’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are oral dosage forms</p>	<p>Strength: Single vs. multiple. Rozerem is available in single strength and may be omitted from a prescription vs. an order for Kazano will require a strength as it is available in multiple strengths.</p>

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/s/

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**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: April 13, 2012

Reviewer(s): Jamie Wilkins Parker, Pharm.D.
Division of Medication Error Prevention and Analysis

Acting Team Leader: Yelena Maslov, Pharm.D.
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Drug Name(s) and Strength(s): (b) (4) (Alogliptin and Metformin) Tablets,
12.5 mg/500 mg and 12.5 mg/1000 mg

Application Type/Number: NDA 203414

Applicant/Sponsor: Takeda

OSE RCM #: 2012-216

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