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RESEARCH**

APPLICATION NUMBER:

022426Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date: October 24, 2012

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Drug Name and Strengths: Oseni (Alogliptin and Pioglitazone) Tablets,
12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg,
25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg

Application Type/Number: NDA 22426

Applicant/Sponsor: Takeda Global Research and Development Center

OSE RCM #: 2012-1776

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Oseni, 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 initial proposed proprietary name for Alogliptin and Pioglitazone Tablets, (b) (4) was found acceptable by DMEPA in OSE # 2008-1803 dated January 6, 2009. However, the original NDA, dated September 19, 2008, received a Complete Response (CR) on September 2, 2009. Subsequently, the Applicant submitted an amendment on July 25, 2011 to address the deficiencies outlined in the CR and resubmitted for review the proprietary name (b) (4). However, the Applicant withdrew the request for review of the proprietary name (b) (4) on October 18, 2012 (b) (4).

On October 18, 2011, the Applicant submitted a review of the proposed proprietary name, Oseni, and DMEPA found the name acceptable in OSE #2011-3954 dated December 23, 2011. On April 25, 2012, the Application received a CR and the Applicant submitted an amendment to address the deficiencies outlined in the CR Letter on July 27, 2012. On August 1, 2012, the Applicant resubmitted the request for review the proposed proprietary name, Oseni.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 18, 2011 proprietary name submission. The Applicant stated that none of the proposed product characteristics have changed since the issuance of the April 2012 CR Letter.

- Established Name: Alogliptin and Pioglitazone
- Indication of Use: Adjunct to diet and exercise to improve glycemic controls in adults with type 2 diabetes mellitus
- Route of administration: Oral
- Dosage form: Fixed-dose combination tablets
- Dose: 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg, 12.5 mg/15 mg, 12.5 mg/30 mg, and 12.5 mg/45 mg
- How Supplied: Bottles of 7 tablets, 30 tablets, 90 tablets, and 500 tablets; (b) (4) blister package of 7 tablets
- Storage: 25°C (77°F); excursions permitted to 15° to 30°C (59°- 86°F)
- Container and Closure systems: HDPE Bottle (b) (4)

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The September 25, 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, Oseni, has no derivation and 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

Ninety-five practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with currently marketed products nor did they appear or sound similar to any currently marketed products. Thirteen of the 32 inpatient participants responded correctly. Misinterpretation occurred with 4 participants confusing the letter 'i' for 'l' and 6 participants confusing the letter 'i' with 't' in Osen*l*. Three of the 33 voice participants responded correctly. The majority of misinterpretations occurred with 23 participants confusing the letter 'e' for 'i' in Os*e*ni and 9 participants confusing the letter 'i' for 'y' in Osen*i*. Twenty-two of the 30 outpatient participants responded correctly. Five participants confused the letter 'e' for 'L' in Os*e*ni. We have considered these variations in our look-alike and sound-alike searches. 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, September 4, 2012 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not provide 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 to Oseni

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Oseni.

For this review, we re-evaluated the previously identified names from OSE review #2011-3954 contained in Table 1. Additionally, we searched for additional names of concern since the last review (see Table 2). Our analysis of the names from previous review and additional twenty names contained in Table 2, considered the information obtained in the previous sections along with their product characteristics. We determined all 20 names will not pose a risk for confusion as described in Appendix D and E.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study) reviewed in OSE #2011-3954					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Ogen	FDA	Riopan	FDA	Orap	FDA
Osier	FDA	Anzemet	FDA	Oscal	FDA
Orexin	FDA	Adagen	FDA	Onfi	FDA
Amsa PD	FDA	Nesina	FDA	Ovcon-50	FDA
Osco	FDA	Oscion	FDA	Ovcon-35	FDA
Agesic	FDA	Oracea	FDA	Opana	FDA
Urese	FDA	Oasis	FDA	Opcon-A	FDA
Cesium	FDA	Aceon	FDA	Oscimin	FDA
Ocean	FDA	(b) (4)	FDA	Oscimin-SR	FDA
Omega-3	FDA	Arava	FDA	Amrix	FDA
Eraxis	FDA	Azor	FDA	Sorine	FDA
Auro	FDA	Oracit	FDA	Droxia	FDA
Look and Sound Similar					
Asendin	FDA	Osenza	FDA	Orencia	FDA

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Orsythia	FDA	Oracin	FDA	Amen	FDA
Anise	FDA	Anurx Anurx HC	FDA	Asacol Asacol HD	FDA
(b) (4)	FDA	Aricin	FDA	Anacin	FDA
Omacor	FDA	Aravis	FDA	Ovral	FDA
Ovice	FDA	Qnasl	FDA	Omnii	FDA
Osier	FDA	Senna	FDA	Ornex	FDA
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Qsymia	FDA	Oxycontin	FDA		

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on September 25, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Metabolism and Endocrinology Products on October 24, 2012, they stated no additional concerns with the proposed proprietary name, Oseni.

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, Oseni, and have concluded that this name is acceptable. If any of the proposed product characteristics as stated in your October 18, 2011 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.

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.

20. Natural Standard (<http://www.naturalstandard.com>)

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

APPENDICES

Appendix A

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

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

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

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

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>
Look-alike	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 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

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

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
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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.

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

The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

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

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

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Oseni	Scripted May Appear as	Spoken May Be Interpreted as
Capital "O"	0, Q, A, U	Oh
lowercase "o"	A, c, e, u	any vowel
lowercase "s"	g, n, r	c, z
lowercase "e"	a, c, e, i, o, u,	any vowel
lowercase "n"	m, u, x, r, h, v	dn, gn, kn, mn, pn
lowercase "i"	e	any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Oseni Study (Conducted on August 24, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Oseni 12.5mg/45mg T po daily</i></p>	<p>Oseni 25 mg/15 mg</p> <p>One tablet by mouth once a day</p> <p>Dispense #30</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Oseni 25mg/15mg T po q day #30</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study

95 People Responded

Study Name: Oseni

Total	32	33	30	95
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
?	1	0	0	1
NO IDEA	1	0	0	1
OCENI	0	1	0	1
OCINE	0	1	0	1

OCINY	0	1	0	1
OFEDI	0	1	0	1
OFENI	0	1	0	1
OFENY	0	1	0	1
OFINEY	0	1	0	1
OFINI	0	1	0	1
OFINY	0	2	0	2
OLSINI	0	1	0	1
OSCINI	0	1	0	1
OSEEDI	0	1	0	1
OSEL	1	0	0	1
OSEMI	1	0	1	2
OSENI	13	3	22	38
OSENIL	2	0	0	2
OSENL	4	0	0	4
OSENL 12.5 MG	1	0	0	1
OSENT	6	0	0	6
OSERIL	2	0	0	2
OSIDI	0	1	0	1
OSIDIE	0	1	0	1
OSINEE	0	1	0	1
OSINEY 25MG-15MG	0	1	0	1
OSINI	0	5	1	6
OSINI??	0	1	0	1

OSINNE	0	1	0	1
OSINNIE	0	1	0	1
OSINNY	0	1	0	1
OSINY	0	3	0	3
OSLMI	0	0	1	1
OSLNI	0	0	5	5
OSSINI	0	1	0	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Oseni	Failure preventions
1.	Orsythia	Ethinyl estradiol and Levonorgestrel	Look	The pair have sufficient orthographic differences
2.	Qsymia	Phentermine and Extended-release Topiramate	Look	The pair have sufficient orthographic differences
3.	Oxycontin	Oxycodone HCl	Look	The pair have sufficient orthographic differences
4.	Anise	Seed derived from plant (Pimpinella anisum)	Look	Product is not a drug. Anise is a seed or essential oil derived from a plant
5.	(b) (4)			
6.	Omacor	Omega-3 Acid Ethyl Esters	Look	International product marketed in Europe and Central America. Marketed in the United States as Lovaza.

No.	Proprietary Name	Active Ingredient	Similarity to Oseni	Failure preventions
7.	Ovice	N/A	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
8.	Osier	American Dogwood	Look	Name identified in Natural Medicine database. Unable to find product characteristics in commonly used drug databases.
9.	Oracin	Benzocaine and Menthol Erythromycin (Hong Kong)	Look	Name identified in Redbook database as Benzocaine and Menthol (deactivated). Name identified in Micromedex as international name for Erythromycin in Hong Kong.
10.	Anurx Anurx HC	Pramoxine HCl, Zinc Oxide, and Phenylephrine HCl Hydrocortisone Acetate	Look	Name identified in Redbook and Google database. Unable to find product characteristics in commonly used drug databases. Anurx and Anurx HC are deactivated.
11.	Aricin	Triamcinolone Acetonide	Look	Name identified in Redbook and Google database. Unable to find product characteristics in commonly used drug databases. Aricin is deactivated.
12.	Aravis	N/A	Look	Name identified in POCA as name entered by safety evaluator in 2003. Not found in AIMS or DARRTS, or in any major drug reference or internet search.

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

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
13.	<p>Amen (Medroxyprogesterone)</p> <p>Dosage form and strength: Oral tablets: 2.5 mg, 5 mg, 10 mg</p> <p>Usual dose: 5 or 10 mg daily for 5 to 10 days, beginning day 16 or 21 of the menstrual cycle</p>	<p>Orthographic similarity: The beginning letter ‘O’ and ‘A’ appear orthographically similar when scripted. Also, both names contain the letter strings ‘en’ in the same position (3, 4).</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p>	<p>Orthographic difference: The letter ‘s’ and ‘m’ appear orthographically different when scripted.</p> <p>Strength: Both Oseni and Amen are available in multiple strengths. Although there is numerical overlap between the strengths (i.e. 12.5 mg/15 mg and 25 mg/15 mg vs. 2.5 mg), Oseni is a combination product where both strengths need to be specified in order to be considered a complete prescription.</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
14.	<p>Qnasl (Beclomethasone)</p> <p>Dosage form and strength: Intranasal spray: 80 mcg/inhalation</p> <p>Usual dose: Two inhalations each nostril once daily (Total dose: 320 mcg/day)</p>	<p>Orthographic similarity: The beginning letter strings ‘Ose’ and ‘Qna’ appear orthographically similar when scripted.</p> <p>Frequency: Both are prescribed once daily</p>	<p>Orthographic difference: The ending letter string ‘ni’ and ‘sl’ appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Qnasl is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p> <p>Dosing: One (1) tablet vs. Two (2) inhalations or spray</p>

No.	<p>Proposed name:</p> <p><i>Oseni</i></p> <p>(Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u></p> <p>12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u></p> <p>Take one tablet by mouth once daily</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>
15.	<p>Asacol and Asacol HD (Mesalamine)</p> <p>Dosage form and strength:</p> <p>Delayed-release oral tablets: 400 mg HD: 800 mg</p> <p>Usual dose:</p> <p>Two 400 mg tablets to be taken 3 times daily for a total daily dose of 2.4 g for a duration of 6 weeks (Max= 1.6 gm daily in divided doses)</p> <p>HD: Two 800 mg tablets 3 times daily with or without food, for a total daily dose of 4.8 g.</p> <p>Asacol HD 800 mg has not been shown to be bioequivalent to 2 Asacol 400 mg tablets.</p>	<p>Orthographic similarity: The beginning letter strings ‘Ose’ and ‘Asa’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p>	<p>Orthographic difference: The ending letter strings ‘ni’ and ‘col’ appear orthographically different when scripted.</p> <p>Strength: An order for Oseni and Asacol will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p> <p>Frequency: Oseni is prescribed once daily (QD, qd, qday) vs. Asacol is prescribed 3 times daily (TID, 3x/day)</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
16.	<p>Senna (Sennosides)</p> <p>Dosage form and strength: Oral tablet: 8.6 mg</p> <p>Usual dose: Bowel evacuation: 130 mg between 2 to 4 pm the afternoon prior to day of procedure. Constipation: 15 mg once daily (maximum 70 mg to 100 mg/day, divided twice daily)</p>	<p>Orthographic similarity: Both names contain the letter string ‘sen’</p> <p>Dosage form and route of administration: Both are available as oral tablets</p> <p>Frequency: Both Oseni and Senna may be prescribed as once daily.</p>	<p>Orthographic difference: The beginning letters ‘O’ and ‘S’ and the ending letter strings ‘ni’ and ‘a’ appear orthographically different from the letter ‘S’ in Senna.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Senna is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
17.	<p>Omnii (Stannous Fluoride)</p> <p>Dosage form and strength: Dental gel: 0.4%</p> <p>Usual dose: Use as directed</p>	<p>Orthographic similarity: Both Oseni and Omnii begin with the letter ‘O’ and the ending letter string ‘ni’ and ‘nii’ appear orthographically similar when scripted.</p>	<p>Orthographic difference: The letter ‘se’ and ‘m’ in appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Omnii is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing. In addition, Oseni is expressed in ‘mg’ vs. Omnii is expressed in ‘%’</p> <p>Dosing: One (1) tablet by mouth vs. apply as directed</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
18.	<p>Anacin (Acetaminophen, Aspirin, and Caffeine)</p> <p>Dosage form and strength: Oral tablets: 250 mg/250 mg/65 mg</p> <p>Usual dose: 2 tablets (500 mg/dose in combination with 500 mg aspirin and 130 mg caffeine) every 6 hours while symptoms persist; do not use for longer than 48 hours</p>	<p>Orthographic similarity: The beginning letter strings ‘Ose’ and ‘Ana’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The ending letter strings ‘ni’ and ‘cin’ appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Anacin is available in single strength and may be omitted.</p> <p>Frequency: Oseni is prescribed once daily (QD, qday) vs. Anacin is prescribed every 6 hours (q6h)</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
19.	<p>Ovral (Lo/Ovral) (Ethinyl estradiol and Norgestrel)</p> <p>Dosage form and strength: Oral tablets: 30 mcg/0.3 mg</p> <p>Usual dose: One tablet by mouth once daily</p>	<p>Orthographic similarity: The beginning letter strings ‘Os’ and ‘Ov’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral tablets.</p> <p>Frequency: Both Oseni and Ovral are prescribed once daily.</p>	<p>Orthographic difference: The letter strings ‘eni’ and ‘ral’ appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Ovral is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>

No.	<p>Proposed name: <i>Oseni</i> (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
20.	<p>Ornex Ornex Maximum Strength (Acetaminophen and Pseudoephedrine HCl)</p> <p>Dosage form and strength: Oral tablet: 325 mg/30 mg Oral tablet: 500 mg/30 mg</p> <p>Usual dose: Two caplets every 4 to 6 hours as needed (maximum: 8 caplets/day)</p>	<p>Orthographic similarity: The beginning letter strings ‘Os’ and ‘Or’ appear orthographically similar when scripted</p> <p>Dosage form and route of administration: Both are available as oral tablets</p>	<p>Orthographic difference: The ending letter strings ‘eni’ and ‘nex’ appear orthographically different when scripted. Also, Ornex is available in 2 formulations (Ornex and Ornex Maximum Strength) which need to be specified in order to be considered a complete prescription.</p> <p>Strength: Both Oseni and Amen are available in multiple strengths. Although there is numerical overlap between the strengths (i.e. 12.5 mg/30 mg and 25 mg/30 mg vs. 325 mg/30 mg and 500 mg/30 mg), Oseni requires both strengths in order to be considered a complete prescription whereas Ornex may be prescribed using the Acetaminophen component since the Pseudoephedrine (30 mg) component is constant.</p> <p>Frequency: Oseni is prescribed once daily (QD, qday) vs. Ornex is prescribed every 4 to 6 hours (q46h)</p>

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/s/

REASOL AGUSTIN
10/24/2012

YELENA L MASLOV
10/24/2012

CAROL A HOLQUIST
10/24/2012

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

Proprietary Name Review--Final

Date: March 27, 2012

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

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

Drug Name and Strength(s): Oseni (Alogliptin and Pioglitazone) Tablets
12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg,
25 mg/15 mg, 25 mg/30 mg, and 25 mg/45 mg

Application Type/Number: NDA 022426

Applicant: Takeda Global Research and Development Center, Inc

OSE RCM #: 2012-451

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3	CONCLUSIONS.....	3
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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Oseni is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed name, Oseni, acceptable in OSE Review 2011-3954, dated December 23, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2011-3954. Since none of the proposed product characteristics were altered, we did not re-evaluate previous names of concern. The searches of the databases yielded two new names ((b)(4) and Qnexa) thought to look or sound similar to Oseni 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 Oseni and lead to medication errors. This analysis determined that the name similarity between Oseni and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the United States Adopted Names (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 USAN stems in the proposed proprietary name, as of March 26, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on March 1, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

REFERENCES

1. OSE Reviews

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

Appendix 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><u>Proposed name:</u> Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>
(b) (4)		

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</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>Qnexa (Phentermine and Topiramate)</p> <p>Dosage form and Strength: Extended-release Capsules: 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg</p> <p>Usual dose: The recommended starting dose is 3.75 mg/23 mg by mouth once daily. The dose can be titrated up to a maximum dose of 15 mg/92 mg by mouth once daily.</p>	<p>Orthographic similarity: The letter string ‘Ose’ and ‘Qne’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p> <p>Frequency of use: Both are taken once daily.</p>	<p>Orthographic difference: The letter string ‘ni’ and ‘xa’ appear orthographically different when scripted.</p> <p>Strength: The strength is required for both names in order to be considered a complete prescription. Although there is an overlap between part of the strength of the products (Oseni 12.5 mg/<u>15 mg</u> vs. Qnexa <u>15 mg</u>/92 mg), the pioglitazone strength (15 mg, 30 mg, and 45 mg) in Oseni is not constant whereas the alogliptin strength remains constant. Thus, pioglitazone strengths must be specified on the prescription, reducing strength similarities between the two products.</p>

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/s/

REASOL AGUSTIN
03/27/2012

YELENA L MASLOV
03/27/2012

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

Proprietary Name Review

Date: December 23, 2011

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

Team Leader Carlos Mena-Grillasca, RPh, Team Leader
Division of Medication Error Prevention and Analysis

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

Drug Name(s): Oseni (Alogliptin and Pioglitazone) Tablets
12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg,
25 mg/15 mg, 25 mg/30 mg, and 25 mg/45 mg

Application Type/Number: NDA 022426

Applicant: Takeda Global Research and Development Center, Inc

OSE RCM #: 2011-3954

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Oseni, 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 initial proposed proprietary name (b) (4) was found acceptable by DMEPA in OSE Review 2008-1803, dated January 6, 2009. The original submission, dated September 19, 2008, received a Complete Response (CR) on September 2, 2009. Subsequently, the Applicant submitted an amendment on July 25, 2011 to address the deficiencies outlined in the CR and resubmitted for review the proprietary name (b) (4). (b) (4) the Applicant withdrew the application for review of the proprietary name (b) (4). Subsequently, the Applicant submitted to review the proposed proprietary name, Oseni, dated October 18, 2011.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 18, 2011 proprietary name submission.

- Established Name: Alogliptin and Pioglitazone
- Indication of Use: Adjunct to diet and exercise to improve glycemic controls in adults with type 2 diabetes mellitus
- Route of administration: Oral
- Dosage form: Fixed-dose combination tablets
- Dose: 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg, 12.5 mg/15 mg, 12.5 mg/30 mg, and 12.5 mg/45 mg
- How Supplied: Bottles of 7 tablets, 30 tablets, 90 tablets, and 500 tablets; (b) (4) blister package of 7 tablets
- Storage: 25°C (77°F); excursions permitted to 15° to 30°C (59°- 86°F)
- Container and Closure systems: HDPE Bottles (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On November 1, 2011 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

Forty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Ten of the 12 inpatient participants responded correctly and no common misinterpretation occurred. One out of the 17 voice participants responded correctly and a common misinterpretation was Osini (n=5), Ossini (n=3), and Ocini (n=2). A common misinterpretation in the voice study was the consonant 's' for 'c' and the vowel 'e' for 'i'. Thirteen out of 14 outpatient participants responded correctly to Oseni. 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, November 3, 2011 e-mail, the Division of Metabolism and Endocrinology (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Oseni. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Oseni 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 not identified by DMEPA and requires further evaluation.

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

Look Similar		Sound Similar		Look and Sound Similar	
Name	Source	Name	Source	Name	Source
Ogen	FDA	Asendin	FDA	Osenza	FDA
Osier	FDA			Orencia	FDA
Orexin	FDA				
Amsa PD	FDA				
Osco	FDA				
Agesic	FDA				
Urese	FDA				
Cesium	FDA				

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

Look Similar		Sound Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Ocean	FDA				
Omega-3	FDA				
Eraxis	FDA				
Riopan	FDA				
Anzemet	FDA				
Adagen	FDA				
Nesina	FDA				
Oscion	FDA				
Oracea	FDA				
Oasis	FDA				
Aceon	FDA				
(b) (4)	FDA				
Arava	FDA				
Azor	FDA				
Orap	FDA				
Oscal	FDA				
Onfi	FDA				
Ovcon-50	FDA				
Ovcon-35	FDA				
Opana	FDA				
Opcon-A	FDA				
Oscimin	FDA				
Oscimin-SR	FDA				
Amrix	FDA				
Sorine	FDA				
Auro	FDA				
Oracit	FDA				
Droxia	FDA				

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

Look Similar		Sound Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Qvar	FDA				
Creon	FDA				
Orinase	FDA				
Urex	FDA				
Ocella	FDA				
Olux	FDA				
Olux-E	FDA				

Our analysis of the 46 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the 46 names will pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Metabolism and Endocrinology via e-mail on November 23, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on December 2, 2011, they stated no additional comments or objections with the proposed proprietary name, Oseni.

3 CONCLUSIONS

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

The proposed proprietary name, Oseni, must be re-reviewed upon submission of the NDA and 90 days before approval of the NDA.

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, Oseni, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 18, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

1. *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 Pharmacy's Fundamental Reference**

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 Book**

Medical Abbreviations Book 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.

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.

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

medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.² The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

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

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
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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 Division of Drug Marketing, Advertising, and Communications (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists,

physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

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

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

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances

FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Oseni	Scripted May Appear as	Spoken May Be Interpreted as
O	0, Q, A, U	Oh
s	g, n, r	c, z
e	a, c, e, i, o, u,	any vowel
n	m, u, x, r, h, v	dn, gn, kn, mn, pn
i	e	any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Oseni Study (Conducted on October 28, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Oseni 12.5mg/15mg 1 tab daily #30</i></p>	<p>Oseni 12.5 mg/15 mg 1 tab daily Disp #30</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Osni 25mg/30mg + tab daily</i></p>	

FDA Prescription Simulation Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Oseni	Oceni	Orseni
Oseni	Ocini	Oseni
Oseni	Ocini	Oseni
Oseni	Ocinnee	Oseni
Oseni	Ociny	Oseni
Oseni	Ofini	Oseni
Oseni	Oseni	Oseni
Oseni	Osini	Oseni
Osmi	Osini	Oseni
	Os inny	Oseni
	Ossini	Oseni
	Ossini	
	Ossini	
	Osyni	

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 Oseni	Failure preventions
Ogen	Estropipate	Look	Ogen is the Canadian brand name for estropipate
Osier	American Dogwood	Look	Name identified in Natural Medicines Database. The name could not be retrieved from any other pharmaceutical databases.
Orexin	Armodafinil	Look	Name identified in Redbook. The name could not be retrieved from any other pharmaceutical databases. Orexin, also called hypocretins, are the common names given to a pair of excitatory neuropeptide hormones in rats brains. Preliminary use data indicates that the name Orexin is not used in prescribing.
Amsa PD	Amsacrine	Look	Amsa PD is the Canadian brand name for Amsacrine
Osco	Not Applicable	Look	Name identified in Redbook. The name could not be retrieved from any other pharmaceutical databases. Osco is a brand name for Albertson's chain stores.
Agesic	Agesic	Look	Name identified in Redbook. The name could not be retrieved from any other pharmaceutical databases. Preliminary use data indicates that the name Agesic is not used in prescribing.
Urese	Benzthiazide	Look	Discontinued product with no available generics. Withdrawn FR Effective: Status date- 8/7/1997
Cesium	Cesium (Chemical Element)	Look	Cesium is a chemical element. Name identified in Redbook. The name could not be retrieved from any other pharmaceutical databases.
Osenza	Not applicable	Look	Name identified in Saegis and United States Patent and Trademark Office (USPTO). The name was abandoned on March 16, 2009 and is indicated as dead. Preliminary use data indicates that the name Osenza is not used in prescribing.
Omega-3	Omega-3	Look	Omega-3 is a nutritional supplement available as an over the counter product. Preliminary use data indicates that the name Omega-3 is not used in prescribing.
Eraxis	Anidulafungin	Look	Lacks sufficient orthographic similarity to result in name confusion.
Riopan	Magaldrate	Look	Lacks sufficient orthographic similarity to result in name confusion.

Proprietary Name	Active Ingredient	Similarity to Oseni	Failure preventions
Anzemet	Dolasetron	Look	Lacks sufficient orthographic similarity to result in name confusion.
Adagen	Pegademase Bovine	Look	Lacks sufficient orthographic similarity to result in name confusion.

(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: Oseni (Alogliptin and pioglitazone) Tablets</p> <p>Strength: 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p>Usual dose: Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Nesina (Alogliptin) Tablets Strength: 6.25 mg, 12.5 mg, 25 mg Usual dose: Take one tablet by mouth once daily</p>	<p>Orthographic similarity: Oseni contains the letter string ‘seni and Nesina contains the letter string ‘esin’ which appears orthographically similar when scripted.</p> <p>Phonetic similarity: Both names contain three syllables. The enunciation of the second syllable ‘sin’ and ‘sen’ sound similar when spoken.</p> <p>Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing (12.5 mg/15 mg vs. 12.5 mg and 25 mg/15 mg vs. 25 mg).</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency of use: Both are taken once daily.</p>	<p>Orthographic difference: ‘O’ and ‘N’ appear orthographically different when scripted. Oseni (5 letters) appear shorter than Nesina (6 letters) when scripted.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Orencia (Abatacept) Injection solution</p> <p>Strength: Subcutaneous solution: 125 mg/mL; Intravenous solution for reconstitution: 250 mg</p> <p>Usual dose: Intravenous (IV): 500 mg to 1000 mg every 2 to 4 weeks after the 1st infusion, then every 4 weeks thereafter; the Subcutaneous: 125 mg given within a day following an intravenous loading dose, then 125 mg subcutaneously once weekly</p>	<p>Orthographic similarity: Both names begin with ‘O’ and have similar shapes when scripted.</p> <p>Strength: Both have multiple strengths and there is numerical overlap between the strengths during prescription writing (25 mg/15 mg vs. 250 mg and 12.5 mg/15 mg vs. 125 mg/mL)</p>	<p>Orthographic difference: Oseni (5 letters) appear shorter than Orencia (7 letters) when scripted.</p> <p>Dosage form and route of administration: Oral tablets vs. Injection solution given subcutaneously and intravenously</p> <p>Dose: One tablets vs. ‘xx’ mg or ‘xx’ mL</p> <p>Frequency of use: Once daily vs. Every 2 to 4 weeks</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Asendin (Amoxapine) Tablets</p> <p>Strength: 25 mg, 50 mg, 100 mg, 150 mg</p> <p>Usual dose: Take 1 to 2 tablets by mouth twice or three times daily. (200 mg to 300 mg per day)</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar when scripted. Both names contain the letter strings ‘sen.’</p> <p>Phonetic similarity: Both names contain three syllables. The enunciation of the second syllable ‘sen’ and last syllable ‘ni’ and ‘din’ sound similar when spoken.</p> <p>Strength: Both have multiple strengths and there is overlap between the strengths during prescription writing (25 mg/15 mg vs. 25 mg).</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: Asendin contains an upstroke which is absent in Oseni. Also, Oseni (5 letters) appears shorter than Asendin (7 letters) when scripted.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Ocean (Sodium Chloride) Nasal Spray</p> <p>Strength: 0.65%</p> <p>Usual dose: Use 2 to 3 sprays in each nostril as needed</p>	<p>Orthographic similarity: Both names begin with ‘O’ and the letter strings ‘cean’ and ‘seni’ appear orthographically similar when scripted.</p>	<p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Ocean is available in single strength and may be omitted. There is no overlap between the strength during prescription writing.</p> <p>Frequency: Once daily vs. as needed</p> <p>Dosage form and route of administration: Oral tablets vs. Nasal spray</p> <p>Dose: One tablets vs. 2 to 3 sprays</p>
<p>Oscion (Benzoyl Peroxide) Topical pads and lotion</p> <p>Strength: Pad: 3%, 6%, 9%; Lotion: 3%, 6%, 9%</p> <p>Usual dose: Pads: Apply in the evening; Lotion: Apply once or twice daily</p>	<p>Orthographic similarity: Both names begin with ‘O’ and the letter strings ‘scion’ and ‘seni’ appear orthographically similar when scripted.</p>	<p>Strength: Both have multiple strengths and there is no overlap between the strengths during prescription writing. Also, the strengths for Oseni are expressed in ‘mg’ and the strengths for Oscion are expressed in ‘%’</p> <p>Dosage form and route of administration: Oral tablets vs. Topical pads and lotion</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Oracea (Doxycycline) Delayed-release capsules</p> <p>Strength: 40 mg</p> <p>Usual dose: Take one capsule by mouth once daily in the morning on an empty stomach, preferably at least 1 hour prior or 2 hours after meals</p>	<p>Orthographic similarity: Both names begin with ‘O’ and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency of use: Both are taken once daily.</p>	<p>Orthographic difference: Oseni (5 letters) appears orthographically shorter than Oracea (6 letters) when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Oracea is available in single strength which may be omitted. There is no overlap between the strengths during prescription writing.</p>
<p>Oasis (Saliva substitute) Oral mouthwash and spray</p> <p>Strength: 2 mg/mL</p> <p>Usual dose: Mouthwash: Rinse with 30 mL twice daily or as needed; do not swallow; Spray: Use 1 to 2 sprays as needed; Maximum 60 sprays per day</p>	<p>Orthographic similarity: Both names begin with ‘O’ and have similar shapes when scripted.</p> <p>Route of administration: Both are oral administration.</p>	<p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Oasis is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p> <p>Dose: One tablets vs. ‘xx’ mL or ‘xx’ spray</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Aceon (Perindopril Erbumine) Tablets</p> <p>Strength: 2 mg, 4 mg, 8 mg</p> <p>Usual dose: Take 4 mg to 8 mg by mouth daily, may be given in 2 divided doses.</p> <p>Maximum: 16 mg per day</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both are taken once daily. Aceon may be given as twice daily.</p>	<p>Strength: An order for Oseni and Aceon will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>
<p>Arava (Leflunomide) Tablets</p> <p>Strength: 10 mg, 20 mg</p> <p>Usual dose: Loading dose: 100 mg (5 tablets of 20 mg) by mouth once daily for 3 days, followed by 20 mg by mouth once daily</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both are taken once daily.</p>	<p>Strength: An order for Oseni and Arava will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Azor (Amlodipine and Olmesartan) Tablets</p> <p>Strength: 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg, 10 mg/40 mg</p> <p>Usual dose: Take 1 tablet by mouth once daily</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both are taken once daily.</p>	<p>Orthographic difference: Oseni (5 letters) appear longer than Azor (4 letters) when scripted. In addition, the letter ‘z’ in Azor may be scripted as a downstroke which may further differentiate the names.</p> <p>Strength: An order for Oseni and Azor will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>
<p>Orap (Pimozide) Tablets</p> <p>Strength: 1 mg, 2 mg</p> <p>Usual dose: Initial: Take 1 to 2 mg by mouth daily; Maintenance: Most patients are maintained at less than 10 mg per day or at less than 0.2 mg/kg/day, whichever is less</p>	<p>Orthographic similarity: Both names begin with ‘O’</p> <p>Frequency of use: Both are taken daily</p>	<p>Orthographic difference: Oseni (5 letters) appears orthographically longer than Orap (4 letters) when scripted. Orap contains a downstroke which is absent in Oseni giving the names different shapes.</p> <p>Strength: An order for Oseni and Orap will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Oscal (Calcium and Vitamin D) Tablets</p> <p>Strength: 500 mg and 400 international units</p> <p>Usual dose: Take one tablet by mouth daily. For persons 51 years old and greater, take one tablet by mouth twice daily</p>	<p>Orthographic similarity: Both names begin with ‘O’</p> <p>Dosage form and Route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both are taken once daily.</p>	<p>Orthographic difference: Oscal contains an upstroke which is absent in Oseni giving the names different shapes.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Oscal is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>
<p>Onfi (Clobazam) Tablets</p> <p>Strength: 5 mg, 10 mg, 20 mg</p> <p>Usual dose: Patients 30 kg or less: start at 5 mg up to 20 mg per day and patients more than 30 kg: start at 10 mg up to 40 mg per day</p>	<p>Orthographic similarity: Both names begin with ‘O’</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: Oseni (5 letters) appears orthographically longer than Onfi (4 letters) when scripted. Onfi contains a downstroke and an upstroke ‘f’ which is absent in Oseni giving the names different shapes.</p> <p>Strength: An order for Oseni and Onfi will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Ovcon-50 and Ovcon-35 (Ethinyl estradiol and Norethindrone) Tablets</p> <p>Strength: Ethinyl estradiol 0.05 mg and norethindrone 1 mg; Ethinyl estradiol 0.035 mg and norethindrone 0.4 mg</p> <p>Usual dose: Take one tablet by mouth once daily</p>	<p>Orthographic similarity: ‘Both names begin with ‘O’ and the letter strings ‘vcon’ and ‘seni’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both are taken once daily.</p>	<p>Orthographic difference: Ovcon contains a modifier which is absent in Oseni. The modifier (50 and 35) is required for a complete prescription.</p> <p>Strength: An order for Oseni will require strength as it is available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Opana (Oxymorphone) Immediate-release tablets, Extended-release (12-hour) tablets, and Injection solution</p> <p>Strength: Immediate-release: 5 mg, 10 mg; Extended-release (12-hour): 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, Injection solution: 1 mg/mL</p> <p>Usual dose: Immediate-release: 10 mg to 20 mg by mouth every 4 to 6 hours; Extended-release: 5 mg by mouth every 12 hours Intramuscular and subcutaneous injection: 1 mg to 1.5 mg, may repeat every 4 to 6 hours as needed</p>	<p>Orthographic similarity: Both names begin with ‘O’</p> <p>Strength: Both are available in multiple strengths and there is overlap between the strengths during prescription writing (12.5 mg/15 mg vs. 15 mg, 12.5 mg/30 mg vs. 30 mg)</p>	<p>Orthographic difference: Opana contains a downstroke which is absent in Oseni giving the names different shapes.</p> <p>Dosage form and route of administration: Oseni is available only as a tablet taken orally while Opana is available as an immediate-release tablet, extended-release tablet, and injection which need to be specified during prescription writing.</p> <p>Frequency: Once daily vs. Every 12 hours or Every 4 to 6 hours as needed</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Opcon-A (Naphazoline hydrochloride and pheniramine Maleate) Ophthalmic solution</p> <p>Strength: 0.027% and 0.3%</p> <p>Usual dose: Instill 1 to 2 drops up to 4 times daily</p>	<p>Orthographic similarity: Both names begin with ‘O’</p>	<p>Orthographic difference: Opcon- A contains a downstroke and a modifier which is absent in Oseni giving the names different shapes.</p> <p>Strength: Both have multiple strengths and there is no overlap between the strengths during prescription writing. Also, the strengths for Oseni are expressed in ‘mg’ and the strengths for Opcon-A are expressed in ‘%’</p> <p>Dosage form and route of administration: Oral tablets vs. ophthalmic solution</p> <p>Dose: One tablet vs. 1 to 2 drops</p> <p>Frequency: Once daily vs. up to 4 times daily</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Oscimin and Oscimin SR (Hyoscyamine) Immediate-release and Extended release (SR) tablets</p> <p>Strength: 0.125 mg, SR: 0.375 mg</p> <p>Usual dose: Take 1 to 2 tablets by mouth every 4 hours as needed; SR: Take 1 to 2 tablets by mouth every 12 hours</p>	<p>Orthographic similarity: Both names begin with ‘O’ and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: Oseni (5 letters) appear shorter than Oscimin (7 letters) when scripted. Oscimin SR contains a modifier which is absent in Oseni. The modifier is required for a complete prescription.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Oscimin and Oscimin SR is available in single strengths and may be omitted.</p> <p>Frequency of use: Once daily vs. Every 4 hours as needed or every 12 hours</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Amrix (Cyclobenzaprine) Extended-release capsules</p> <p>Strength: 15 mg, 30 mg</p> <p>Usual dose: Take one capsule by mouth daily.</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar and have similar shapes when scripted.</p> <p>Strength: Both have multiple strengths and there is overlap between the strengths during prescription writing (<i>25 mg/15 mg vs. 15 mg, 25 mg/30 mg vs. 30 mg</i>).</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: ‘seni’ and ‘mrix’ appear orthographically different when scripted. In addition, Amrix contains a cross stroke in the last position which is absent in Oseni.</p> <p>Frequency of use: Preliminary usage data shows that Amrix is commonly prescribed as once daily but is also prescribed as every 6 hours, every 4 hours, every 8 hours, or every 12 hours as needed</p>
<p>Sorine (Sotalol HCl) Tablets</p> <p>Strength: 80 mg, 120 mg, 160 mg, 240 mg</p> <p>Usual dose: 160 to 320 mg per day, given in 2 or 3 divided doses.</p>	<p>Orthographic similarity: Oseni and Sorine have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: ‘S’ and ‘R’ appear orthographically different when scripted.</p> <p>Strength: An order for Oseni and Sorine will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Auro (Carbamide peroxide) Otic Solution Strength: 6.5%</p> <p>Usual dose: Instill 5 to10 drops twice daily up to 4 days, tip of applicator should not enter ear canal; keep drops in ear for several minutes by keeping head tilted and placing cotton in ear</p>	<p>Orthographic similarity: ‘O’ and ‘A’ appear orthographically similar and have similar shapes when scripted.</p>	<p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Auro is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p> <p>Dose: One tablets vs. 5 to 10 drops</p>
<p>Oracit (Sodium Citrate and Citric Acid) Oral solution Strength: 490 mg and 640 mg per 5 mL</p> <p>Usual dose: Take 10 to 30 mL with water four times daily, after meals and at bedtime</p>	<p>Orthographic similarity: Both names begin with ‘O’</p>	<p>Orthographic difference: Oracit contains an upstroke which is absent in Oseni giving the names different shapes.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Oracit is available in single strength. There is no overlap between the strengths during prescription writing.</p> <p>Dose: One tablet vs. ‘xx’ mL</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Droxia (Hydroxyurea) Capsules</p> <p>Strength: 200 mg, 300 mg, 400 mg</p> <p>Usual dose: Chronic myeloid leukemia: 20 mg/kg to 30 mg/kg once daily; Sickle-cell: 15 mg/kg per day. Dosage for an average adult = 900 mg to 1800 mg</p>	<p>Orthographic similarity: ‘O’ and ‘D’ appear orthographically similar and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency of use: Both are taken once daily.</p>	<p>Strength: An order for Oseni and Droxia will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>
<p>Qvar (Beclomethasone) Inhalation Solution</p> <p>Strength: 40 mcg, 80 mcg</p> <p>Usual dose: Inhale 1 to 2 puffs twice daily. Maximum dose: 320 mcg twice daily</p>	<p>Orthographic similarity: ‘O’ and ‘Q’ appear orthographically similar and have similar shapes when scripted.</p>	<p>Strength: An order for Oseni and Qvar will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p> <p>Dosage form: Tablets vs. Inhalation solution</p> <p>Dose: One tablets vs. 1 to 2 puffs</p> <p>Frequency: Once daily vs. Twice daily</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Creon (Pancrealipase) Capsules</p> <p>Strength: Lipase 3000 units, protease 9500 units, and amylase 15,000 units</p> <p>Lipase 6000 units, protease 19,000 units, and amylase 30,000 units</p> <p>Lipase 12000 units, protease 38,000 units, and amylase 60,000 units</p> <p>Lipase 24,000 units, protease 76,000 units, and amylase 120,000 units</p> <p>Usual dose: Take one capsule by mouth three times daily with each meal while consuming greater than or equal to 100 g of fat per day</p>	<p>Orthographic similarity: ‘O’ and ‘C’ appear orthographically similar and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Strength: An order for Oseni and Creon will require strength as they are available in multiple strengths. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Orinase (Tolbutamide) Tablets</p> <p>Strength: 500 mg</p> <p>Usual dose: Take one-half tablet (250 mg) to 6 tablets (3000 mg) by mouth in the morning or in divided doses. Divided doses may improve gastrointestinal tolerance.</p>	<p>Orthographic similarity: Both names begin with ‘O’ and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency: Both may be taken once daily. Orinase is recommended to be taken in divided doses.</p>	<p>Orthographic difference: Oseni (5 letters) appear shorter than Orinase (7 letters) when scripted.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Orinase is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>
<p>Urex (Methenamine) Tablets</p> <p>Strength: 1000 mg</p> <p>Usual dose: Take one tablet by mouth twice daily</p>	<p>Orthographic similarity: ‘O’ and ‘C’ appear orthographically similar and have similar shapes when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p>	<p>Orthographic difference: Urex contains a cross stroke in the last position which is absent in Oseni.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Urex is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Ocella (Ethinyl estradiol 0.03 mg and drospirenone 3 mg) Tablets</p> <p>Usual dose: Take one tablet by mouth once daily</p>	<p>Orthographic similarity: Both names begin with ‘O’ and the letter strings ‘se’ and ‘ce’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as solid oral dosage forms.</p> <p>Frequency of use: Both are taken once daily.</p>	<p>Orthographic difference: Ocella contains 2 upstrokes ‘ll’ which are absent in Oseni giving the names different shapes.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Ocella is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p>

<p><u>Proposed name:</u></p> <p>Oseni (Alogliptin and pioglitazone) Tablets</p> <p><u>Strength:</u> 12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth once daily</p>		<p>How supplied: Bottles of 90-count and 500-count; 7-tablets and bottle of 30-count professional use (not for sale)</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; (name confusion)</p>
<p>Olux, Olux-E External Foam Clobetasol Propionate and Clobetasol Propionate Emulsion</p> <p>Strength: 0.05%</p> <p>Usual dose: Apply a thin layer to the affected skin areas twice daily and rub in gently and completely</p>	<p>Orthographic similarity: Both names begin with ‘O’</p>	<p>Orthographic difference: Olux contains an upstroke which is absent in Oseni giving the names different shapes. Olux also contains a modifier which is absent in Oseni. The modifier ‘E’ is required for a complete prescription.</p> <p>Strength: Multiple vs. single. An order for Oseni will require strength as it is available in multiple strengths vs. Olux is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing.</p> <p>Dosage form and route of administration: Oral tablets vs. Topical emulsion and foam</p>

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/s/

REASOL AGUSTIN
12/23/2011

CARLOS M MENA-GRILLASCA
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CAROL A HOLQUIST
12/23/2011

**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: October 20, 2011

Reviewer(s): Jibril Abdus-Samad, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Todd Bridges, RPh, Team Leader
Division of Medication Error Prevention and Analysis

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

Drug Name(s): (b) (4) (Alogliptin and Pioglitazone) Tablets
12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg,
25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg

Application Type/Number: NDA 022426

Applicant: Takeda Pharmaceuticals America, Inc

OSE RCM #: 2011-2599

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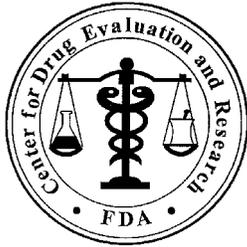
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JIBRIL ABDUS-SAMAD
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TODD D BRIDGES
10/21/2011

CAROL A HOLQUIST
10/21/2011



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: January 6, 2009

To: Mary Parks, MD, Director
Division of Metabolism and Endocrinology Products

Through: Todd Bridges, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

From: Zachary Oleszczuk, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name(s): (b) (4) (Alogliptin and Pioglitazone) Tablets
25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg,
12.5 mg/15 mg, 12.5 mg/30 mg, and 12.5 mg/45 mg

Application Type/Number: NDA # 22-426

Applicant: Takeda

OSE RCM #: 2008-1803

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Todd Bridges
1/6/2009 08:15:41 PM
DRUG SAFETY OFFICE REVIEWER
Also signing for Zachary Oleszczuk.

Denise Toyer
1/7/2009 07:59:49 AM
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Carol Holquist
1/7/2009 01:10:23 PM
DRUG SAFETY OFFICE REVIEWER