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APPLICATION NUMBER:

022271Orig1s000

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

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

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

Drug Name and Strengths: Nesina (Alogliptin) Tablets, 6.25 mg, 12.5 mg, and 25 mg

Application Type/Number: NDA 22271

Applicant/Sponsor: Takeda Global Research and Development Center

OSE RCM #: 2012-1775

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nesina, 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 name Nesina, was found acceptable by DMEPA in OSE reviews #2008-59 and #2008-2085. Subsequently, the NDA received a Complete Response (CR) Letter in June 2009 in which the Agency requested that the Applicant conduct a safety trial in compliance with FDA guidance to Industry release in 2008. The Applicant re-submitted the NDA on July 25, 2011 and included a request for review of the proprietary name, Nesina. DMEPA found the proprietary name, Nesina, acceptable in OSE #2011-2601 dated October 19, 2011. On April 25, 2012, the NDA received another CR Letter 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 submitted a request for review the proposed proprietary name, Nesina. Of note, no product characteristics have changed since the previous DMEPA name review.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 21, 2007 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
- 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: Oral tablets
- Dose: 6.25 mg, 12.5 mg, 25 mg
- How Supplied: For 6.25 mg tablets, bottles of 30 tablets and 90 tablets. For 12.5 mg and 25 mg, bottles of 30 tablets, 90 tablets, and 500 tablets
- Storage: 25°C (77°F); excursions permitted to 15° to 30°C (59°- 86°F)
- Container and Closure systems: HDPE Bottles; All unit of use bottles (i.e. 30-count, 90-count) (b) (4) with foil induction seal. The pharmacy bulk 500-count bottle (b) (4).

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of 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, Nesina, has no intended meaning. The proposed name 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

Ninety-six 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. Thirty-one of the 33 inpatient participants responded correctly. Misinterpretation occurred with 1 participant confusing the letter 'a' for 'i' in NesinA and 1 participant confusing the letter 'i' with 'li' in NesIna. Four of the 33 voice participants responded correctly. The majority of misinterpretations occurred with 14 participants confusing the letter 'e' for 'a' NEsina. Twenty-eight of the 30 outpatient participants responded correctly. Misinterpretation occurred with 1 participant misinterpreted 'n' for 'v' in NesiNa and the letter 'e' for 'i' in NEsina. 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 forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names to Nesina

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

For this review, we re-evaluated the previously identified names from OSE review #2008-59 and #2008-2085 contained in Table 1 and OSE review #2011-2601 contained in Table 2. Additionally, we searched for additional names of concern since the last review (see Table 3). 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 29 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 #2008-59 and #2008-2085 and re-reviewed with no additional concerns					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Nesacaine	Mesine	Mesna	Vesicare	Tasigna	Niaspan
Nescuta	Nesina*	Mirena	(b) (4)	Nexium	Niacin
Mesnex	(b) (4)	Nasin	TriNessa	Visine	Extina
Renova	Vesprin	Mexsana	Resine		
Look and Sound Similar					
Nasonex	Niacor	Lessina			

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study) reviewed in OSE #2011-2601 and re-reviewed no additional concerns					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Mesnex	EPD	Narcan	SE	Vesicare	EPD
Mucinex	EPD	Navane	SE	Nasonex	EPD
Nevanac	EPD	Norvir	SE	Necon	EPD
Niacin	EPD	Kresira	SE	Veronica	EPD
Visine	EPD	Humira	SE	Rescula	EPD

* This name has been registered in foreign countries by the same applicant and appears to be for the same indication.

*** Note: This is proprietary and confidential information that should not be released to the public. ***

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study) reviewed in OSE #2011-2601 and re-reviewed no additional concerns					
Neosar	EPD	Luzena	SE	Kariva	EPD
Mircera	EPD	Vanos	EPD	Lexiva	EPD
Nesacaine	EPD	Nexaris	SE	Menveo	EPD
Nescon PD	EPD	Nexium	EPD	Mirena	EPD
Nervine	EPD	Nasin	EPD	(b) (4)	EPD
Niacor	EPD	Vimovo	EPD	Neoscan	EPD
Vermox	EPD	Extina	EPD	Moxeza	EPD
Menest	EPD	(b) (4)	EPD	Incivo***	SE
(b) (4)	EPD	(b) (4)	EPD	Vascor	SE
Dezina	SE				
		Look and Sound Similar			
Mesna	EPD	Lessina	EPD	Revina	EPD
Nesina	EPD				

Table 3: 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>
Mag-Oro	FDA	Natazia	FDA	Necon PD	FDA
Mag-SR	FDA	Anexsia	FDA	Navane	FDA
Magan	FDA	Nanovm	FDA	Niravam	FDA
Marax DF	FDA	Nu-Iron	FDA	Ranexa	FDA
Mascon	FDA	Nuromax	FDA	Rezira	FDA
Mason	FDA	Nariz	FDA	Renova	FDA
Neo AC	FDA	Narvox	FDA	Nasacort	FDA
Nogenic	FDA	Neevo	FDA	Na-zone	FDA
Noroxin	FDA	Norco	FDA	Narcan	FDA
Norvasc	FDA	Rescon (MX, DM, GG)	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 Division of Metabolism and Endocrinology Products on October 24, 2012, they stated no additional concerns with the proposed proprietary name, Nesina.

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, Nesina, 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.

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

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

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

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

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

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

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

Type of Similarity	Considerations when Searching the Databases		
	<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
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names 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, Nesina	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'N'	M, V, U, W, R	DN, GN, KN, MN, PN, M
lowercase 'n'	m, r, s, u, x, h	dn, gn, kn, m, mn, pn
lowercase 'e'	i, a, l, o, u, p	Any vowel
lowercase 's'	G, 5, g, n	x
lowercase 'i'	e	y
lowercase 'n'	M, r, s, u, x, h	dn, gn, kn, m, mn, pn
lowercase 'a'	el, ci, cl, d, o, u	Any vowel

Appendix C: Prescription Simulation Samples and Results

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

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Nesina 12.5mg T tab po daily</i></p>	<p>Nesina 25 mg</p> <p>One by mouth once a day</p> <p>Dispense #30</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Nesina 25mg + po qday #30</i></p>	

Study Name: Nesina

192 People Received Study

96 People Responded

Study Name: Nesina

Total	33	33	30	96
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
??	0	1	0	1
MASENA	0	1	0	1
NACEENA	0	1	0	1
NACENA	0	2	0	2
NACINA	0	2	0	2
NASCINA???	0	1	0	1
NASEENA	0	2	0	2
NASENA	0	2	0	2
NASINA	0	2	0	2
NASSINA	0	1	0	1
NECINA	0	2	0	2
NEFINA	0	2	0	2
NERSEENA	0	1	0	1
NERSINA	0	1	0	1
NESCINA	0	1	0	1
NESEENA	0	1	0	1
NESENA	0	1	0	1
NESINA	31	4	28	63
NESINI	1	0	0	1
NESIVA	0	0	1	1

NESLINA	1	0	0	1
NESSENA	0	1	0	1
NESSINA	0	3	0	3
NISINA	0	0	1	1
NOSENA	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 Nesina	Failure preventions
1.	Mag-Oro	Magnesium Orotate	Look	The pair has sufficient orthographic differences. Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
2.	Mag-SR	Magnesium Chloride	Look	The pair has sufficient orthographic differences.
3.	Magan	N/A	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
4.	Marax DF	Ephedrine sulfate, Hydroxyzine HCl, and Theophylline	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
5.	Mascon	Aluminum Hydroxide and Magnesium Carbonate	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
6.	Mason	Spirolactone and Hydrochlorothiazide	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.

No.	Proprietary Name	Active Ingredient	Similarity to Nesina	Failure preventions
7.	Neo AC	Codeine Phosphate, Pseudoephedrine HCl, and Pyrilamine Maleate	Look	The pair has sufficient orthographic differences.
8.	Nogenic	N/A	Look	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
9.	Noroxin	Norfloxacin	Look	The pair has sufficient orthographic differences.
10.	Norvasc	Amlodipine	Look	The pair has sufficient orthographic differences.
11.	Natazia	Estradiol and dienogest	Look	The pair has sufficient orthographic differences.
12.	Anexsia	Hydrocodone Bitartrate and Acetaminophen	Look	The pair has sufficient orthographic differences.
13.	Nanovm	Multivitamin, Minerals, Iron, and Nutraceuticals	Look	The pair has sufficient orthographic differences.
14.	Nu-Iron	Iron polysaccharide	Look	The pair has sufficient orthographic differences.
15.	Nuromax	Doxacurium Chloride	Look	The pair has sufficient orthographic differences.

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

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Niravam (Alprazolam) Dosage form and strength: Oral dispersible tablet: 0.25 mg, 0.5 mg, 1 mg, 2 mg Usual dose: 1 tablet (0.25 to 0.5 mg) 3 times a day	Orthographic similarity: The beginning letter strings ‘Nes’ and ‘Nir’ and ‘na’ and ‘va’ appear orthographically similar when scripted. Strength: Both are available in multiple strengths and there is numerical overlap between strengths (25 mg vs. 0.25 mg) Dosage form and route of administration: Both are available as oral tablets.	Orthographic difference: The letter ‘i’ in Nesina and ‘a’ in Niravam in position 4 appear orthographically different when scripted. In addition, the ending letter strings ‘ina’ and ‘avam’ appear orthographically different when scripted. Frequency: Nesina is prescribed once daily (qd, qday, QD) vs. Niravam is prescribed three times daily (TID, 3x/day)
2.	Ranexa (Ranolazine) Dosage form and strength: 12-hour extended release oral tablets: 500 mg and 1000 mg Usual dose: 1 tablet (500 mg) by mouth twice daily, up to 1000 mg twice daily	Orthographic similarity: The letters in ‘Nesina’ and ‘Ranexa’ appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral tablets.	Strength: Both an order for Nesina and Ranexa will require strength as it is available in multiple strengths. There is no overlap in strengths.

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	Rezira (Hydrocodone Bitartrate and Pseudoephedrine) Dosage form and strength: Oral solution: 5 mg/60 mg Usual dose: Adults 18 years old and older: 5 mL by mouth every 4 to 6 hours, up to 20 mL/day	Orthographic similarity: The letter strings ‘Nesina’ and ‘Rezira’ appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral dosage forms.	Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Rezira is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Rezira is prescribed every 4 to 6 hours

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
4.	Renova (Tretinoin) Dosage form and strength: External Cream: 0.02% Usual dose: Gently wash face with a mild soap, pat the skin dry, and wait 20 to 30 minutes before applying. Apply a pea-sized amount of cream to cover the entire face. Apply to the face once a day in the evening, using only enough to cover the entire affected area lightly. Take caution to avoid contact with eyes, ears, nostrils, and mouth.	Orthographic similarity: The letters in ‘Nesina’ and ‘Renova’ appear orthographically similar when scripted. Frequency: Both are prescribed once daily	Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Renova is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Dosing: 1 tablet vs. apply or use as directed

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
5.	Nasacort (Triamcinolone Acetonide) Dosage form and strength: Nasal aerosol solution: 55 mcg/inhalation Usual dose: 2 sprays (220 mcg) in each nostril once daily. Age 2 to 5 years: 110 mcg or 1 spray in each nostril once daily.	Orthographic similarity: The beginning letter string 'Nes' and 'Nas' appear orthographically similar when scripted. Frequency: Both are prescribed once daily	Orthographic difference: The ending letter strings 'ina' and 'acort' appear orthographically different when scripted. Strength: Both are available in multiple strengths but there is no overlap between the strengths.

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Navane (Thiothixene) Dosage form and strength: Oral capsule: 2 mg, 10 mg, 20 mg Usual dose: Mild conditions: 2 mg by mouth 3 times per day. Increase to 15 mg/day if indicated. Severe conditions: 5 mg twice daily. Maintenance dosage: 20 mg to 30 mg per day. Increase to 60 mg/day if indicated. Exceeding a total daily dosage of 60 mg/day rarely increases the beneficial response.	Orthographic similarity: The beginning letter strings 'Ne' and 'Na' and ending letter string 'na' and 'ne' appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral dosage forms	Orthographic difference: The letter strings 'si' and 'va' appear orthographically different when scripted. Strength: Both are available in multiple strengths. There is no overlap between the strengths.

No.	<p>Proposed name: <i>Nesina</i> (<i>Alogliptin</i>)</p> <p>Strength: 6.25 mg, 12.5, and 25 mg</p> <p>Usual dose: 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>
7.	<p>Nariz (Phenylephrine HCl and Guaifenesin)</p> <p>Dosage form and strength: Oral solution: 7.5 mg/200 mg</p> <p>Usual dose: Greater than or equal to 12 years old: 10 mL every 4 to 6 hours, up to 40 mL/day; 6 to 12 years old: 5 mL every 4 to 6 hours, up to 20 mL/day; 2 to 6 years old: 2.5 mL every 4 to 6 hours, up to 10 mL/day</p>	<p>Orthographic similarity: The beginning letter strings ‘Nesi’ and ‘Nari’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms</p>	<p>Orthographic difference: The ending letter strings ‘na’ and ‘z’ appear orthographically different when scripted.</p> <p>Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Nariz is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing</p> <p>Frequency: Nesina is prescribed once daily vs. Nariz is prescribed every 4 to 6 hours</p>

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8.	Narvox (Acetaminophen and Oxycodone) Dosage form and strength: Oral tablets: 500 mg/10 mg Usual dose: 1 to 2 tablets by mouth every 4 to 6 hours as needed.	Orthographic similarity: The beginning letter strings 'Ne' and 'Na' appear orthographically similar when scripted. Frequency: Both are prescribed once daily Dosage form and route of administration: Both are available as oral tablets.	Orthographic difference: The ending letter strings 'sina' and 'rvox' appear orthographically different when scripted. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Narvox is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Narvox is prescribed every 4 to 6 hours

No.	<p>Proposed name: <i>Nesina</i> (<i>Alogliptin</i>)</p> <p><u>Strength:</u> 6.25 mg, 12.5, and 25 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>
9.	<p>Rescon MX (Phenylephrine, Chlorpheniramine, and Methscopolamine)</p> <p>Dosage form and strength: Extended-release capsule: 40 mg/8 mg/2.5 mg</p> <p>Usual dose: Greater than or equal to 12 years: 1 capsule every 12 hours;</p>	<p>Orthographic similarity: The beginning letter strings ‘Nes’ and ‘Res’ appear orthographically similar when scripted.</p> <p>Dosage form and route of administration: Both are available as oral dosage forms.</p>	<p>Orthographic difference: The ending letter strings ‘ina’ and ‘con’ appear orthographically different when scripted. Rescon is available in multiple formulations which require the use of the modifier (MX, DM, and GG) for a complete prescription.</p> <p>Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Rescon is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing</p>

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
10.	Rescon DM (Dextromethorphan, Chlorpheniramine, and Pseudoephedrine) Dosage form and strength: Oral solution: 10 mg/2 mg/30mg per 5 mL Usual dose: Greater than or equal to 12 years old: 10 mL every 4 to 6 hours, up to 40 mL/day; 6 to 12 years old: 5 mL every 4 to 6 hours, up to 20 mL/day	Orthographic similarity: The beginning letter strings ‘Nes’ and ‘Res’ appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral dosage forms.	Orthographic difference: The ending letter strings ‘ina’ and ‘con’ appear orthographically different when scripted. Rescon is available in multiple formulations which require the use of the modifier (MX, DM, and GG) for a complete prescription. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Rescon DM is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Rescon DM is prescribed every 4 to 6 hours

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
11.	Rescon GG (Phenylephrine and Guaifenesin) Dosage form and strength: Oral solution: 5 mg/100 mg Usual dose: Greater than or equal to 12 years old: 10 mL every 4 to 6 hours, up to 40 mL/day; 6 to 12 years old: 5 mL every 4 to 6 hours; up to 20 mL/day	Orthographic similarity: The beginning letter strings 'Nes' and 'Res' appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral dosage forms.	Orthographic difference: The ending letter strings 'ina' and 'con' appear orthographically different when scripted. Rescon is available in multiple formulations which require the use of the modifier (MX, DM, and GG) for a complete prescription. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Rescon is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Rescon GG is prescribed every 4 to 6 hours

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	Norco (Hydrocodone Bitartrate and Acetaminophen) Dosage form and strength: Oral tablets: 5 mg/325 mg, 7.5 mg/325 mg, and 10 mg/325 mg Usual dose: 1 to 2 tablets by mouth every 4 to 6 hours	Orthographic similarity: The beginning letter strings 'Ne' and 'No' appear orthographically similar when scripted. Dosage form and route of administration: Both are available as oral tablets.	Orthographic difference: The ending letter string 'sina' and 'rco' appear orthographically different when scripted. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Rescon is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Norco is prescribed every 4 to 6 hours
13.	Neevo (Multivitamins) Dosage form and strength: Oral tablets/capsule Usual dose: Take 1 tablet by mouth once daily	Orthographic similarity: Both names begin with the letter string 'Ne' Frequency: Both are prescribed once daily Dosage form and route of administration: Both are available as oral tablets.	Orthographic difference: The ending letter string 'sina' and 'evo' appear orthographically different when scripted. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Neevo is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
14.	Na-zone (Sodium Chloride) Dosage form and strength: Nasal spray: 0.75% Usual dose: Use 2 to 3 sprays in each nostril as needed	Orthographic similarity: The beginning letter strings 'Nes' and 'Naz' appear orthographically similar when scripted.	Orthographic difference: The ending letter strings 'ina' and 'one' appear orthographically different when scripted. Strength: Multiple vs. single. An order for Nesina will require strength as it is available in multiple strengths vs. Na-zone is available in single strength and may be omitted. There is no overlap between the strengths during prescription writing Frequency: Nesina is prescribed once daily vs. Na-zone is as needed. Dosing: 1 tablet vs. 2 to 3 sprays

No.	Proposed name: <i>Nesina</i> <i>(Alogliptin)</i> Strength: 6.25 mg, 12.5, and 25 mg Usual dose: Take one tablet by mouth once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
15.	Narcan (Naloxone HCl) Dosage form and strength: Injection solution: 4 mg/mL and 1 mg/mL Usual dose: Opioid overdose: Initial dose is 0.4 mg to 2 mg intravenously, intramuscularly, or subcutaneously; may repeat at 2 to 3-minute intervals. Post-op depression: Initial dosage: Inject in increments of 0.1 mg to 0.2 mg IV at 2 to 3-minute intervals to the desired degree of reversal.	Orthographic similarity: The beginning letter strings 'Nes' and 'Nar' appear orthographically similar when scripted.	Orthographic difference: The ending letter strings 'ina' and 'can' appear orthographically different when scripted. Frequency: Nesina is prescribed once daily vs. Naloxone is as needed or now. Dosing: 1 tablet vs. xx mg or mL

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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 1, 2012

Reviewer: Sarah K. Vee, Pharm.D.
Division of Medication Error Prevention and Analysis

Team Leader (Acting): Yelena Maslov, Pharm.D.
Division of Medication Error Prevention and Analysis

Drug Name and Strength(s): Nesina (alogliptin) 6.25 mg, 12.5 mg, 25 mg Tablets

Application Type/Number: NDA 022271

Applicant/sponsor: Takeda

OSE RCM #: 2012-450

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Nesina, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Nesina, acceptable in OSE Review 2011-2601, dated October 19, 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 2011-2601. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded five new names (Merrem, (b) (4), and Vusion), thought to look similar to Nesina 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 the identified names and lead to medication errors. This analysis determined that the name similarity between Nesina and the identified names was unlikely to result in medication error for the reasons presented in Appendices A and B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Nesina, as of February 28, 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, Nesina, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Nesina, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. **OSE Review 2011-2601, Proprietary Name Review for Nesina**

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

Proprietary Name	Active Ingredient	Similarity to drug name	Failure Preventions
(b) (4)	levonorgestrel and ethinyl estradiol	orthographic	Applicant withdrew the name; product was approved under the name Orsythia on May 11, 2011
(b) (4)	alcaftadine	orthographic	Applicant withdrew the name; product was approved under the name Lastacast July 28, 2010.

Appendix B: FMEA Table

Proposed name: Nesina (alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, and 25 mg oral tablets Usual Dose: 1 tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Merrem (meropenem) - 500 mg, 1 gram per vial powder for injection - 250 mg to 1 gram every 8 to 24 hours IV for adults - 10 mg to 40 mg/kg every 8 hours for pediatric patients	Orthographic Similarities - 'N' and 'M' may appear similar when scripted - Both names have the letter 'e' at the 2 nd position - End letter strings ('sina' vs. 'rrem') may appear similar when scripted	Differing Product Characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 500 mg, 1 gram with no overlap)

(b) (4)

<p>Proposed name: Nesina (alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, and 25 mg oral tablets</p> <p>Usual Dose: 1 tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Vusion (miconazole, petrolatum, and zinc oxide)</p> <ul style="list-style-type: none"> - 0.25 %/81.35 %/15 % topical ointment - Apply a thin layer to the affected are at each diaper change for 7 days 	<p>Orthographic Similarities</p> <ul style="list-style-type: none"> - ‘Ne’ and ‘Vu’ may appear similar when scripted - Both names have the letter string ‘si’ at the same position 	<p>Differing Product Characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. single strength with no overlap) - Dose (1 tablet vs. amount needed to cover the affected area) - Frequency of Administration (once daily vs. at each diaper change)

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/s/

SARAH K VEE
03/01/2012

YELENA L MASLOV
03/01/2012

**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: October 19, 2011

Reviewer(s): Anne C. Tobenkin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Lubna Merchant, PharmD
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, R.Ph.
Division of Medication Error Prevention and Analysis

Drug Name(s): Nesina (Alogliptin) Tablets

Strengths: 6.25 mg, 12.5 mg, 25 mg

Application Type/Number: 022271

Applicant/sponsor: Takeda

OSE RCM #: 2011-2601

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nesina, 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 name Nesina, was found acceptable by DMEPA in OSE reviews # 2008-59 and # 2008-2085. Subsequently, the NDA received a Complete Response in June 2009 in which the Agency requested that the Applicant conduct a safety trial in compliance with FDA guidance to Industry release in 2008. The Applicant re-submitted the NDA on July 25, 2011 and included a new proprietary name review. Of note, no product characteristics have changed since the previous DMEPA name review.

1.2 PRODUCT INFORMATION

Nesina (alogliptin) is an inhibitor of the dipeptidyl-peptidase-4 (DPP-4) enzyme and is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Nesina is indicated for:

- Monotherapy
- Combination therapy, with an insulin secretagogue or insulin to provide adequate glycemic control

The recommended dose of Nesina is 25 mg once daily, as monotherapy or as combination therapy. Nesina may be taken with or without food. Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with End-Stage Renal Disease requiring dialysis.

Nesina will be available as film-coated tablets containing 6.25 mg, 12.5 mg, and 25 mg of alogliptin. The 6.25 mg tablets will be available in bottles of 30 tablets and 90 tablets. The 12.5 mg and 25 mg tablets will be available in bottles of 30 tablets, 90 tablets, and 500 tablets.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The September 29, 2011 United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name is composed of a single word, Nesina. Per the Applicant, the proprietary name has no intended meaning. The proposed name does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that is misleading or can contribute to medication error.

2.2.4 FDA Name Simulation Studies

Thirty eight practitioners participated in DMEPA's prescription studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies. The most common misinterpretations in the written study were: 'M' or 'V' for 'N', 'i' for 'e' and including a 'z' or 't' in the middle of the name. The most common misinterpretations in the voice study included 'a' and 'i' for 'e', 'v', 'c' or 'ss' for 's' and 'e' or 'ee' for 'i'. Of note, one respondent who misinterpreted the name for 'Nicena', commented that the name was "to close to Mirena".

2.2.5 Comments from Other Review Disciplines

In response to the OSE, August 15, 2011 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed name, Nesina. Table 1, on page 3, lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Nesina, identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines.

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

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>
Mesnex	EPD	None found		Mesna	EPD
Mucinex	EPD			Nesina	EPD
Nevanac	EPD			Lessina	EPD
Niacin	EPD			Revina	EPD
Visine	EPD				
Neosar	EPD				
Mircera	EPD				
Nesacaine	EPD				
Nescon PD	EPD				
Nervine	EPD				
Nexium	EPD				
Nasin	EPD				
Vesicare	EPD				
Nasonex	EPD				
Necon	EPD				
Veronica	EPD				
Rescula	EPD				
Kariva	EPD				
Lexiva	EPD				
Menveo	EPD				
Mirena	EPD				
(b) (4)	EPD				
Niacor	EPD				
Vermox	EPD				
Vimovo	EPD				
Extina	EPD				
Neoscan	EPD				
Moxeza	EPD				

Look Similar	
Menest	EPD
(b) (4)	EPD
(b) (4)	EPD
(b) (4)	EPD
Incivo****	SE
Vascor	SE
Dezina	SE
Narcan	SE
Navane	SE
Norvir	SE
Kresira	SE
Humira	SE
Luzena	SE
Vanos	EPD
Nexaris	SE

Our analysis of the 47 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics for the names. We determined the 47 names will not pose a risk for confusion as described in Appendix D through E.

DMEPA communicated these findings to the DMEP via e-mail on October 17, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP they stated no additional concerns with the proposed proprietary name, Nesina.

3 CONCLUSIONS

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

3.1 COMMENTS TO THE APPLICANT

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

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

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

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.

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

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

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

USPTO provides information regarding patent and trademarks.

9. *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.

10. *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.

11. *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.

12. *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.

13. *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.

14. *Red Book Pharmacy's Fundamental Reference*

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

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

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

16. *Medical Abbreviations Book*

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by DDMAC. DDMAC 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. DDMAC provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

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

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

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

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

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.² The 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>
	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or

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

Look-alike		Overlapping product characteristics	electronic communication <ul style="list-style-type: none"> 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
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of

multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DDMAC's decision on the name. The

primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’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.

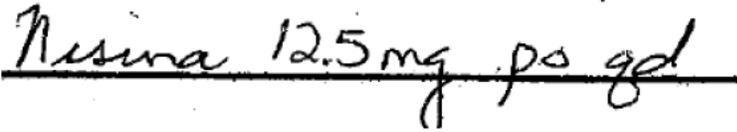
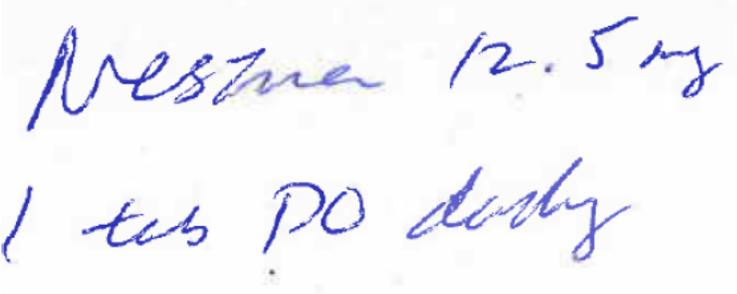
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, NAME	Scripted May Appear as	Spoken May Be Interpreted as
N	M, V, H	“M”
e	i, a, o, u	“a”, “i”, “u”
s	r, v, n, i	“c”, “z”, “sc”
i	e, c	“y”, “ee”
n	s, m	“m”
a	e, o, u,	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Rx Prescription Simulation Study (Conducted on August 5, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Nesina 12.5 mg po Qdaily</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses.

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
NISINA	NESTUER	NAVENA
MISINA	VESTNER	NESEENA
NISINA	NESZRIA	NIFEENA
NISINA	VESZNA	NICENA
NISINA	NESTUA	NECINA
NISINA	NESZNA OR NESTNA	NISSENA
NISINA	VESTRIA	NESINA
NISINA	NESTRA	NEFINA
NISINA	NESZNA	NECENA
NISINA	NESSINA	NESINA
NISINA	NESTRIA	NYTEENA
	VESTUEN	
	NESTARA 12.5 MG	
	MESZINE	
	NESTRA	
	VESTRIA	

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 Nesina	Failure preventions
Rescula	Unoprostone isopropyl	Orthographic	Product is no longer marketed in the U.S., no generic available
(b) (4)	Ciclesonide	Orthographic	(b) (4) name found unacceptable in OSE review # 06-0030. Product approved and marketed with proprietary name, Omnaris
(b) (4)	Norethindrone	Orthographic	(b) (4) found unacceptable in OSE review # 2010-1630 due to the presence (b) (4)
(b) (4)	Hydroxprogesterone	Orthographic	(b) (4) name not reviewed, product approved and marketed with primary name, Makena
Nesina	Alogliptin	Orthographic and phonetic	Name under evaluation in this review
Incivo***	Telaprevir	Orthographic	(b) (4) the product is approved and marketed with the name Incivek
Vascor	Bepidil	Orthographic	Product is no longer marketed in the U.S., and no generic is available
Dezina	N/A	Orthographic	Name found in USPTO and Saegis, but not found in other commonly used drug databases

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: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Mesnex (Mesna)</p> <ul style="list-style-type: none"> - 1 g per vial, injection - 400 mg oral tablets - Three bolus doses given with each Ifosfamide dose, equal to 20% of the Ifosfamide dosage. Administered at the time of Ifosfamide administration and 4 and 8 hours after each dose - Mesna tablets are given orally in a dosage equal to 40% of the Ifosfamide dose, 2 hours and 6 hours after each dose 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘M’ appear similar when scripted - Both names are similar in length - Both names have only one upstroke - Nether name has a downstroke - Both names have ‘es’ in the same location <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina does not have a cross-stroke vs. Mesnex ends with a cross-stroke <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 400 mg, single strength, not required on prescription) - Dose (one tablet vs. dose based on percentage of Ifosfamide dose) - Frequency of administration (once daily vs. with Ifosfamide dose and 4 and 8 hours after each dose)
<p>Mucinex (Guaifenisin)</p> <ul style="list-style-type: none"> - 600 mg, 1200 mg oral tablets - 100 mg/5 mL oral solution - 1 tablet by mouth every 12 hours as needed - ½ teaspoon to 2 teaspoons by mouth every 4 hours as needed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘M’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke - Both names have ‘in’ in the same location <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina does not have a cross-stroke vs. Mucinex ends with a cross-stroke <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 600 mg, 1200 mg tablets or 100 mg/5 mL solution) - Frequency of administration (once daily vs. two to six times a day as needed)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Nevanac (Nepafenac)</p> <ul style="list-style-type: none"> - 0.1% ophthalmic suspension - One drop into the affected eye(s) three times daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither names has a downstroke 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina appears shorter when scripted vs. Nevanac <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 0.1%, single strength, not required on prescription) - Dose (one tablet vs. one drop) - Frequency of administration (once daily vs. three times daily)
<p>Niacin (Nicotinic acid)</p> <ul style="list-style-type: none"> - 50 mg, 100 mg, 250 mg, 500 mg oral tablet - Starting dose of 250 mg by mouth at bedtime, increasing up to 1.5 to 3 g by mouth per day in 2 or 3 divided doses 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with same letter, ‘N’ - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) - Numerical overlap (25 mg vs. 250 mg) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - The ending ‘ina’ appears different when scripted vs. ‘cin’ in Niacin <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily vs. twice to three times per day after titration period) - Strength (6.25 mg, 12.5 mg, 25 mg vs. 50 mg, 100 mg, 250 mg, 500 mg)
<p>Visine (Glycerin, Hypromellose, Poly-Ethylene Glycol and Tetrahydrozoline or Oxymetazoline)</p> <ul style="list-style-type: none"> - 0.2%/0.36%/1%, 0.2%/0.36%/1%/0.05%, 0.025% ophthalmic solutions - One drop into affected eye(s) as needed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke - Both names are similar in length 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strengths (6.25 mg, 12.5 mg, 25 mg vs. 0.2%/0.36%/1%, 0.2%/0.36%/1%/0.05%, 0.025%, or no strength on prescription) - Dose (one tablet vs. one drop) - Frequency of administration (once daily vs. as needed)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Neosar (Cyclophosphamide) Product discontinued, generic available - 100 mg, 200 mg, 500 mg, 1 g, 2 g per vial - 40 mg/kg to 50 mg/kg intravenously in divided doses over 2 to 5 days - 3 mg/kg to 5 mg/kg intravenously twice weekly - 10 mg/kg to 15 mg/kg intravenously every 7 to 10 days - 2.5 mg/kg to 3 mg/kg intravenously daily for 60 to 90 days	Orthographic similarity - Both names begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke - Both names are similar in length Overlapping product characteristics - Frequency of administration (once daily)	Differing product characteristics - Dose (one tablet vs. weight based regimen) - Route of administration (oral vs. intravenous) - Dosage form (tablet vs. infusion)
Mircera (Methoxy Polyethylene Glycol Epoetin Beta) - 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 1000 mcg per vial or 50 mcg, 75 mcg, 100 mcg, 150 mcg, 200 mcg, 250 mcg, 400 mcg, 600 mcg, 800 mcg prefilled syringe - 0.6 mcg/kg subcutaneously or intravenously every 2 weeks	Orthographic similarity - 'N' and 'M' appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke Overlapping product characteristics - Numerical overlap (25 mg vs. 250 mcg)	Differing product characteristics - Dose (one tablet vs. weight based dose, one syringe) - Route of administration (oral vs. intravenous or subcutaneous, needs to be specified on order) - Frequency of administration (everyday vs. once every two weeks)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Nesacaine (Chloroprocaine) - 1%, 2% injection solution - 11 mg/kg to 14 mg/kg intravenously as a single injection or continuous infusion	Orthographic similarity - Both names begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke	Orthographic differences - Nesina is six letters vs. Nesacaine is nine letters making it appear longer when scripted Differing product characteristics - Dose (one tablet vs. weight based dose) - Strength (6.25 mg, 12.5 mg, 25 mg vs. 1% or 2%) - Frequency of administration (once daily vs. one time as needed)
Nescon PD (Guaifenesin and Phenylephrine) - 275 mg/25 mg oral tablet - 1 to 2 tablets by mouth once or twice daily	Orthographic similarity - Both names begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke Overlapping product characteristics - Dosage form (tablet) - Route of administration (oral)	Orthographic differences - Nesina does not have a modifier vs. Nescon PD has a modifier which adds to the length of the name Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 275 mg/25 mg, single strength, not required on prescription)
Nervine (Diphenhydramine) - 25 mg oral tablet - 1 to 2 tablets by mouth every 4 to 6 hours as needed	Orthographic similarity - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke Overlapping product characteristics - Strength (25 mg) - Dose (1 tablet) - Dosage form (tablet) - Route of administration (oral)	Differing product characteristics - Frequency of administration (once daily vs. every 4 to 6 hours) - Preliminary use data suggests that this name is not frequently utilized during prescribing and dispensing

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Nexium (Esomeprazole)</p> <ul style="list-style-type: none"> - 20 mg, 40 mg oral capsule - 10 mg, 20 mg, 40 mg oral granules - 20 mg, 40 mg per vial for injection - 10 mg to 40 mg once daily or 40 mg twice daily - 10 mg to 40 mg intravenously once daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (solid oral; capsule, tablet) - Frequency of administration (once daily) - Route of administration (oral) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina does not have a cross-stroke vs. Nexium has a cross-stroke <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 20 mg, 40 mg)
<p>Nasin (Oxymetazoline)</p> <ul style="list-style-type: none"> - 0.05% nasal spray - 1 spray each nostril as needed, not to be used for more than 3 days 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke - Both names have 'sin' in same location <p>Phonetic similarity</p> <ul style="list-style-type: none"> - The first syllables "Na" vs. "Ne" sound similar - Both have the same sound "seen" for the second syllable 	<p>Phonetic similarity</p> <ul style="list-style-type: none"> - Nesina is three syllables vs. Nasin is two syllables making the names sound different when pronounced <p>Orthographic differences</p> <ul style="list-style-type: none"> - 'a' at the end of Nesina makes the name appear longer vs. Nasin ends with 'n' <p>Differing product characteristics</p> <ul style="list-style-type: none"> - strength (6.25 mg, 12.5 mg, 25 mg vs. 0.05%, single strength, not required on prescription) - Frequency of administration (once daily vs. as needed) - Dose (one tablet vs. one spray)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Vesicare (Solifenacin succinate)</p> <p>- 5 mg, 10 mg oral tablets</p> <p>- 1 tablet by mouth once daily</p>	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina is six letters vs. Vesicare is eight letters making it appear longer when scripted <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 5 mg, 10 mg)
<p>Nasonex (Mometasone)</p> <p>- 17 g per bottle nasal spray, 50 mcg per spray</p> <p>- 1 to 2 sprays in each nostril once daily</p>	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both begin with the same letter, ‘N’ - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Frequency of administration (once daily) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina is composed of six letters and appears shorter when scripted vs. Nasonex which is seven letters and contains wider letters <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 50 mcg per spray, single strength, not required on prescription)
<p>Necon (Norethindrone and Ethinyl estradiol or Norethindrone and Mestranol)</p> <p>- 7/7/7, 1/35 oral tablets, 28 day pack</p> <p>- 1/50 oral tablets, 28 day pack</p> <p>- One tablet by mouth once daily or as directed</p>	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both begin with the same letters, ‘Ne’ - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina has six letters and a letter that follows the final ‘n’ vs. Necon has five letters and ends with ‘n’ <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 7/7/7, 1/35, 1/50)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Veronica (Veronica officinalis)</p> <ul style="list-style-type: none"> - ground parts of plant - one cup tea by mouth 2 to 3 times daily or as lavage or compress daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina is six letters vs. Veronica is eight letters making it appear longer when scripted <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet vs. parts of a plant) - Strength (6.25 mg, 12.5 mg, 25 mg vs. no strength representation for this product) - Frequency of administration (once daily vs. two to three times daily)
<p>Kariva (Desogestrel/Ethinyl estradiol and Ethinyl estradiol)</p> <ul style="list-style-type: none"> - 0.15mg/0.02 mg, 0.01 mg oral tablets, 28 day pack - One tablet by mouth once daily or use as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names have only one upstroke - Neither name has a downstroke - Both names are similar in length <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - ‘N’ in Nesina and ‘K’ in Kariva do not resemble one another when scripted. Additionally, there are no name pairs that begin with ‘N’ and ‘K’ on the ISMP list of confused names <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. single strength, not required on prescription)
<p>Lexiva (Fosamprenavir)</p> <ul style="list-style-type: none"> - 700 mg oral tablet, 50 mg/mL oral suspension - 1400 mg by mouth once (with ritonavir) or twice daily or 700 mg by mouth twice daily with ritonavir or 18 mg/kg to 30 mg/kg by mouth twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names have only one upstroke - Neither name has a downstroke - Both names are similar in length - Both names end with ‘a’ <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Frequency of administration (once daily) - Route of administration (oral) - Dose (one tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina does not have a cross-stroke vs. Lexiva has a cross-stroke <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 700 mg, single strength, not required on prescription) - Frequency of administration (once daily vs. Lexiva dosed once daily has a dose of two tablets, which exceeds the recommended dose of one tablet for Nesina)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Menveo (Menigococcal vaccine) - 2 vials per one dose - 0.5 mL intramuscular injection once, can be administered again 2 months after first vaccine	Orthographic similarity - 'N' and 'M' appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke	Differing product characteristics - Dose (one tablet vs. 0.5 mL, or two vials) - Frequency of administration (once daily vs. one time) - Strength (6.25 mg, 12.5 mg, 25 mg vs. no strength)
Mirena (Levonorgestrel) - 52 mg intrauterine device - 1 device inserted intravaginally by a healthcare professional every 5 years	Orthographic similarity - 'N' and 'M' appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke - Both names have same ending 'na'	Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 52 mg, single strength, not required on prescription) - Route of administration (oral vs. intrauterine) - Frequency of administration (once daily vs. once every 5 years)
Niacor (Niacin) - 500 mg oral tablet - 250 mg (1/2 tablet) for 4 to 7 days then titrate to 1 g (2 tablets) by mouth once daily three times daily	Orthographic similarity - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke Overlapping product characteristics - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet)	Orthographic differences - The ending 'ina' in Nesina appears different when scripted vs. 'cor' in Niacor Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 500 mg, single strength, not required on prescription)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Vermox (Mebendazole) Product discontinued, generic available</p> <ul style="list-style-type: none"> - 100 mg chewable tablets - 1 tablet by mouth twice daily for 3 days or one tablet by mouth once (pediatric dose) 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina does not have a cross-stroke vs. Vermox ends with a cross-stroke <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 100 mg, single strength, not required on prescription)
<p>Vimovo (Naproxen and Esomeprazole)</p> <ul style="list-style-type: none"> - 375 mg/20 mg, 500 mg/20 mg oral tablets - 1 tablet by mouth twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘V’ appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Dose (one tablet) 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 375 mg/20 mg, 500 mg//20 mg) - Frequency of administration (once daily vs. twice daily)
<p>Extina (Ketoconazole)</p> <ul style="list-style-type: none"> - 2% foam, 50 g and 100 g canisters - Apply to affected area twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names have the same ending ‘ina’ - Both names are 6 letters and similar in length 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - Nesina has no cross-strokes vs. Extina has two cross-strokes - ‘N’ in Nesina does not resemble ‘E’ in Extina <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 2%, single strength, not required on prescription) - Frequency of administration (once daily vs. twice daily)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Neoscan (Gallium citrate) - 6.6 mCi, 8.8 mCi, 13.2 mCi, 19.8 mCi per kit - 2 mCi to 5 mCi intravenous injection one time prior to procedure	Orthographic similarity - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke	Orthographic differences - Nesina has six letters and appears shorter when scripted due to the narrow letters vs. Neoscan which has seven letters Differing product characteristics - Dose (6.25 mg, 12.5 mg, 25 mg vs. 2 mCi to 5 mCi) - Route of administration (oral vs. intravenous) - Frequency of administration (once daily vs. in clinic prior to procedure)
Moxeza (Moxifloxacin) - 0.5% ophthalmic solution - 1 drop in the affected eye twice daily for 7 days	Orthographic similarity - 'N' and 'M' appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke - Both names end with 'a'	Orthographic differences - Nesina does not have a cross-stroke vs. Moxeza has a cross-stroke Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 0.5%, single strength, not required on prescription) - Frequency of administration (once daily vs. twice daily) - Dose (one tablet vs. one drop)
Vanos (Fluocinonide) - 0.1% cream, 30 g, 60 g, 120 g tube - Apply a thin layer to affected are once or twice daily	Orthographic similarity - 'N' and 'V' appear similar when scripted - Both names have only one upstroke - Neither name has a downstroke Overlapping product characteristics - Frequency of administration (once daily)	Orthographic differences - Nesina is six letters vs. Vanos is five letters and appears shorter when scripted Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 0.1%, single strength, not required in prescription) - Dose (one tablet vs. thin layer)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Menest (Esterified estrogens) - 0.3 mg, 0.625 mg, 1.25 mg, 2.5 mg oral tablets - 0.3 mg to 7.5 mg by mouth once daily in cycles or 1.25 mg to 2.5 mg by mouth three times daily	Orthographic similarity - 'N' and 'M' appear similar when scripted - Both names are similar length Overlapping product characteristics - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) - Numerical overlap (6.25 mg, 12.5 mg, 25 mg vs. 0.625 mg, 1.25 mg, 2.5 mg)	Orthographic differences - Nesina have one upstroke vs. Menest has two upstrokes - Nesina does not have a cross-stroke vs. Menest has one cross-stroke

(b) (4)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Mesna</p> <ul style="list-style-type: none"> - 1 g per vial, injection - 400 mg oral tablets - Three bolus doses given with each Ifosfamide dose, equal to 20% of the Ifosfamide dosage at the time of administration and 4 and 8 hours after each dose - Mesna tablets are given orally in a dosage equal to 40% of the Ifosfamide dose, 2 hours and 6 hours after each dose 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘M’ appear similar when scripted - Both names have one upstroke - Neither name has a downstroke <p>Phonetic similarity</p> <ul style="list-style-type: none"> - The first three letters “Nes” and “Mes” lend a similar sound to the beginning of the name - Both names end with the same sound “na” <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) 	<p>Phonetic differences</p> <ul style="list-style-type: none"> - Nesina has three syllables vs. Mesna has two syllables <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 400 mg, single strength, not required on prescription) - Dose (one tablet vs. dose based on percentage of Ifosfamide dose) - Frequency of administration (once daily vs. with Ifosfamide dose and 4 and 8 hours after each dose)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Lessina 28 (Ethinyl estradiol and Levonorgestrel)</p> <ul style="list-style-type: none"> - 0.02 mg/0.1 mg oral tablets, 28 day pack - One tablet by mouth once daily or as directed 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘L’ resemble one another when scripted - Both names have one upstroke - Neither name has a downstroke - Both names are composed of the same letters <p>Phonetic similarity</p> <ul style="list-style-type: none"> - Both names are three syllables - Both names have the same stresses - Both names have the sound “ee” for the middle syllable - both names end with the sound “nah” <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Dosage form (tablet) - Route of administration (oral) - Frequency of administration (once daily) - Dose (one tablet) 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - The first letter ‘N’ in Nesina does not resemble the first letter ‘L’ in Lessina - Nesina appears shorter when scripted vs. Lessina <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 28, single strength, not required on prescription) - Strength designation (Nesina will have a ‘mg’ designation following the numbers vs. Lessina does not have a ‘mg’ designation associated with the number ‘28’)

<p>Proposed name: Nesina (Alogliptin)</p> <p>Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences</p>
<p>Revina (Castor oil, Peru balsam, Trypsin)</p> <ul style="list-style-type: none"> - 788 mg/87 mg/90 USP units per g topical ointment - Apply to wounds twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘R’ appear similar when scripted - Both names have one upstroke - Neither name has a downstroke - Both names end with ‘ina’ <p>Phonetic similarity</p> <ul style="list-style-type: none"> - Both names are three syllables - Both names have the sound “ee” for the middle syllable - Both names end with the sound “nah” 	<p>Phonetic differences</p> <ul style="list-style-type: none"> - The first sound of Nesina, “N” sounds different than “R” of Revina - The second syllable starts with the sound “s” in Nesina vs. “v” in Revina <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 788 mg/87 mg/90 USP units per g, single strength, not required on prescription) - Frequency of administration (once daily vs. twice daily)
<p>Narcan (Nalaxone)</p> <ul style="list-style-type: none"> - 0.4 mg/mL, 1 mg/mL injection solution - 0.4 mg to 2 mg intravenously, subcutaneously or intramuscularly every 2 to 3 minutes, not to exceed 10 mg 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both begin with the same letter, ‘N’ - Both names have only one upstroke - Neither name has a downstroke - Both names are similar length 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral vs. intravenous, intramuscular, subcutaneous, needs to be specified on order) - Frequency of administration (once daily vs. every 2 to 3 minutes as needed for overdose) - Dose (one tablet vs. 0.4 mg to 2 mg)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
Navane (Thiothixene) - 1 mg, 2 mg, 5 mg, 10 mg, 20 mg oral capsule - 2 mg by mouth three times daily, titrate up to 60 mg per day in divided doses	Orthographic similarity - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke - Both names are similar length Overlapping product characteristics - Dosage form (oral solid, tablet, capsule) - Route of administration (oral) - Dose (one tablet/capsule)	Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 1 mg, 2 mg, 5 mg, 10 mg, 20 mg) - Frequency of administration (once daily vs. three times daily)
Norvir (Ritonavir) - 100 mg oral capsule or tablet, 80 mg/mL oral solution - 50 mg to 600 mg by mouth once or twice daily	Orthographic similarity - Both begin with the same letter, 'N' - Both names have only one upstroke - Neither name has a downstroke - Both names are similar length Overlapping product characteristics - Dosage form (oral solid, tablet, capsule) - Route of administration (oral) - Dose (one tablet/capsule) - Frequency of administration (once daily)	Differing product characteristics - Strength (6.25 mg, 12.5 mg, 25 mg vs. 100 mg, 80 mg/mL)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
<p>(b) (4) (Acilidinium)</p> <ul style="list-style-type: none"> - 400 mcg per inhalation, multi-dose dry powder inhaler - One inhalation by mouth twice daily 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names have one upstroke - Neither name has a downstroke - Both names are similar in length 	<p>Orthographic differences</p> <ul style="list-style-type: none"> - ‘N’ in Nesina and (b) (4) do not resemble one another when scripted. Additionally, there are no name pairs that begin with ‘N’ and (b) (4) on the ISMP list of confused names <p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 400 mcg per inhalation, single strength, not required on prescription) - Frequency of administration (once daily vs. twice daily) - Dosage form (tablet vs. powder for inhalation)
<p>Humira (Adalimumab)</p> <ul style="list-style-type: none"> - 20 mg, 40 mg pen, syringe - 20 mg or 40 mg subcutaneously every other week 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - ‘N’ and ‘H’ appear similar when scripted - Both names have one upstroke - Neither names have a downstroke - Both names are similar in length 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 20 mg, 40 mg) - Route of administration (once daily vs. every other week) - Route of administration (oral vs. subcutaneous) - Dosage form (tablet vs. injection solution, pen or syringe)
<p>Luzena (Bedaquiline)</p> <ul style="list-style-type: none"> - 100 mg oral tablets - 4 tablets (400 mg) by mouth once daily for 14 days then 2 tablets (200 mg) 3 times per week for 22 weeks 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names have only one upstroke - Neither name has a downstroke - Both names are similar in length - Both names end with ‘na’ <p>Overlapping product characteristics</p> <ul style="list-style-type: none"> - Route of administration (oral) - Frequency of administration (once daily) - Dosage form (tablet) 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 100 mg, although the strength is obtainable, 100 mg of Nesina exceeds the maximum recommended dose of 25 mg per day) - Dose (once tablet vs. 2 or 4 tablets)
<p>Nexaris (Ciclesonide)</p> <ul style="list-style-type: none"> - 37 mcg per actuation nasal spray - One spray into each 	<p>Orthographic similarity</p> <ul style="list-style-type: none"> - Both names begin with ‘Ne’ - Neither name has a downstroke 	<p>Differing product characteristics</p> <ul style="list-style-type: none"> - Strength (6.25 mg, 12.5 mg, 25 mg vs. 37 mcg per actuation, single strength, not required on prescription) - Route of administration (oral vs. each nostril)

Proposed name: Nesina (Alogliptin) Strengths and Dosage form: 6.25 mg, 12.5 mg, 25 mg oral tablets Usual Dose: One tablet by mouth once daily	Cause of Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences
nostril once daily	- Both names have one upstroke Overlapping product characteristics - Frequency of administration (once daily)	

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/s/

ANNE C TOBENKIN
10/19/2011

LUBNA A MERCHANT
10/19/2011

CAROL A HOLQUIST
10/19/2011



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: September 15, 2008

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

Thru: Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

From: Kellie Taylor, PharmD, MPH, Team Leader
Jinhee J. Lee, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name, Label, and Labeling Review

Drug Name: Nesina (Alogliptin) Tablets
6.25 mg, 12.5 mg, 25 mg

Application Type/Number: IND 69,707
NDA 22-271

Applicant: Takeda Global Research & Development Center, Inc.

OSE RCM #: 2008-59, 2008-2085

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1 INTRODUCTION

This memorandum is written in response to the Division of Medication Error Prevention and Analysis Proprietary Name and Label Review of Nesina for the Division of Metabolic and Endocrinology Products. I have reviewed the safety evaluator's comments and disagree with the final conclusion that the proposed proprietary name Nesina is unacceptable. My conclusion is supported by the Division Director, Deputy Director, and also by the proprietary name risk assessment of Nesina provided by the Applicant in support of the proposed name.

2 MATERIAL REVIEWED

I have reviewed the comments provided by the safety evaluator in OSE Review 2008-59, 2008-2085, and the independent risk assessment of the proposed name conducted by (b) (4) (dated June 2007).

3 DISCUSSION

In total, the safety evaluator reviewed 25 product names thought to present a risk of confusion with Nesina and concluded through Failure Modes and Effects Analysis the similarity between Nesina and Lessina-28 was likely to result in medication error. I agree with the safety evaluator's conclusions for 24 of the 25 names, but disagree with the safety evaluator's assessment regarding the risk of Nesina and Lessina-28 name confusion.

The name, Lessina-28, was identified by the medication error staff and in the (b) (4) analysis as a name that looks and sounds similar to Nesina. Lessina-28 (Levonorgestrel/ Ethinylestradiol) is an oral contraceptive product. The safety evaluator and I agree that Lessina-28 and Nesina have a number of orthographic and phonetic similarities introduced by the five overlapping letters (e, s, i, n, a) which are placed similarly in the words (end in '-ina', contain '-es-' in the prefix).

The reviewer notes product similarities, including: frequency of administration (once daily), dosage form (tablet), and route of administration (oral). The reviewer also notes that the "number '25' resembles '28' and vice versa" and expresses concern that if a prescription is written for "Nesina 25 mg" confusion with Lessina-28 may result. On this basis, the safety evaluator determined through analysis of the failure mode that the similarity of the names, Nesina and Lessina-28, in conjunction with overlapping product characteristics, was likely to result in medication errors in the usual practice setting.

However, it is my opinion that the safety evaluator failed to take into account several important considerations. First, I believe there is some orthographic and phonetic distinction afforded by the different beginning letters ('L' versus 'N') which may help differentiate these names when written or spoken. The reviewer does not acknowledge the phonetic distinction introduced by these letters when spoken, and finds the letters to be orthographically similar when written.

Additionally, although the numerals 25 and 28 may look similar to one another when scripted, the reviewer fails to acknowledge that the unit "mg" may afford some visual distinction between the strength and quantity designations. Moreover, the reviewer does not describe any phonetic similarity associated with these numerals when spoken. Lastly, Nesina will be marketed in two other strengths (6.25 mg and 12.5 mg) which may help to further differentiate these products.

Collectively, these considerations have led me to believe that the differences of the names Lessina-28 and Nesina is unlikely to result in medication errors in the usual practice setting.

4 CONCLUSIONS AND RECOMMENDATIONS

Based on my analysis, I conclude that the name, Nesina, does not appear to be vulnerable to medication errors and thus I have no objections to this name. The Director, Deputy Director, and I concur with the remainder of the comments provided in the review regarding the labeling and labeling, and DMEPA recommends that the comments provided in section 5.2 of the safety evaluator's review be forwarded to the Applicant.

We would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion if needed. Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard review.

EXECUTIVE SUMMARY

The Division of Medication Error Prevention and Analysis (DMEPA) does not recommend the use of the proprietary name, Nesina, for this product. The results of the Proprietary Name Risk Assessment found that the proposed name, Nesina, has overwhelming orthographic and phonetic similarities to Lessina-28, a marketed drug product in the United States. The FMEA indicates that the proposed name appears to be vulnerable to name confusion that could lead to medication errors.

1 BACKGROUND

1.1 INTRODUCTION

This review was written in response to a request from the Division of Metabolism and Endocrinology Products for assessment of the proprietary name “Nesina” regarding potential name confusion with other proprietary or established drug names.

Additionally, container labels, carton and insert labeling were provided for evaluation to identify areas that could lead to medication errors. The applicant also submitted an independent trade name assessment by (b) (4).

1.2 PRODUCT INFORMATION

Nesina (alogliptin) is an inhibitor of the dipeptidyl-peptidase-4 (DPP-4) enzyme and is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Nesina is indicated for:

- Monotherapy
- Combination therapy, when the following agents do not provide adequate glycemic control:
 - a peroxisome proliferator-activated receptor gamma agonist (e.g. thiazolidinediones), either alone or in combination with metformin or a sulfonylurea
 - metformin
 - a sulfonylurea
 - insulin, either alone or in combination with metformin

The recommended dose of Nesina is 25 mg once daily, as monotherapy or as combination therapy. Nesina may be taken with or without food. Dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with End-Stage Renal Disease requiring dialysis.

Nesina will be available as film-coated tablets containing 6.25 mg, 12.5 mg, and 25 mg of alogliptin. The 6.25 mg tablets will be available in bottles of 30 tablets and 90 tablets. The 12.5 mg and 25 mg tablets will be available in bottles of 30 tablets, 90 tablets, and 500 tablets.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the DMEPA staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and label, labeling, and/or packaging risk assessment (see 2.2 Container, Carton Label, and Insert Label Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. 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

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Nesina, and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, and ANDA products currently under review by the Agency.

For the proprietary name, Nesina, the medication error staff of DMEPA search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). DMEPA also conducts internal CDER prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.3).

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.3). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.² FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap, or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. As such, the Staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since 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 drug name include, but are not limited to established name of the proposed product, the proposed indication, 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. 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.³

2.1.1 Search Criteria

The medication error staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

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

² Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

For this review, particular consideration was given to drug names beginning with the letter ‘N’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.⁴⁵

To identify drug names that may look similar to Nesina, the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (6 letters), upstrokes (1, capital letter ‘N’), down-strokes (none), cross-strokes (none), and dotted letters (1, “i”). Additionally, several letters in Nesina may be vulnerable to ambiguity when scripted, including the letter ‘N’ may appear as ‘M’, ‘H’, ‘R’, ‘U’, ‘W’, or ‘S’; lower case ‘a’ appear as a lower case ‘u’ or ‘o’. As such, the Staff should also consider these alternate appearances when identifying drug names that may look similar to Nesina.

When searching to identify potential names that may sound similar to Nesina, the medication error staff search for names with similar number of syllables (3), stresses (NE-sin-a or ne-SIN-a or ne-sin-A), consonant sound pronunciation (“Neh” versus “Nay” or “sin” versus “seen”, “sign”, “zeen”, “zign”), and placement of vowel and consonant sounds. In addition, the letter ‘N’ in Nesina may be subject to interpretation when spoken and may be misinterpreted as ‘M’. As such, the Staff also considers these alternate pronunciations when identifying drug names that may sound similar to Nesina. The applicant’s intended pronunciation of the proprietary name is as follows: nes-see’-na.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the medication error staff were provided with the following information about the proposed product: the proposed proprietary name (Nesina), the established name (alogliptin), proposed indication (adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus), strength (6.25 mg, 12.5 mg, 25 mg), dose (25 mg once daily, with dose being adjusted for patients with moderate to severe renal insufficiency and in patients with End-Stage Renal Disease requiring dialysis), frequency of administration (once daily), route (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics the medication error staff general take into consideration.

Lastly, the medication error staff also consider the potential for the proposed 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. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the medication error staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.1.1 Databases and information sources

The proposed proprietary name, Nesina, was provided to the medication error staff of DMEPA to conduct a search of 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 Nesina using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 6. To complement the process, the medication error staff use 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

⁴ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

⁵ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the medication error staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.1.2 CDER Expert Panel Discussion

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the product and the proprietary name, Nesina. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of the DMEPA staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

The pooled results of the medication error staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

2.1.2 CDER Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Nesina 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 a total of 124 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Nesina in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 124 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 send their interpretations of the orders via e-mail to the medication error staff.

Figure 1. Nesina Study (conducted on October 23, 2007)

HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Prescription:</u></p> <p>Nesina 6.25 mg #30 1 tablet by mouth daily</p>	<p>Nesina 6.25 mg Dispense #30 1 tablet by mouth daily.</p>
<p><u>Inpatient Medication Order:</u></p> <p>Nesina 6.25mg po daily</p>	

2.1.3 External Proprietary Name Risk Assessment

For this product, the applicant submitted an independent risk assessment of the proposed proprietary name conducted by a consulting firm. The medication error staff conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in the medication error staff's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk assessment of the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the medication error staff's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, we provide a detailed explanation of these differences.

2.1.4 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk 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.⁶ When applying FMEA to assess the risk of a proposed proprietary name, the Division of Medication Error Prevention seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and 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 look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

⁶ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. 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 evaluation, and studies, and identifies potential failure modes by asking: “Is the name Nesina convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?” An affirmative answer indicates a failure mode and represents a potential for Nesina to be confused with another proprietary or established drug name because of look- or sound-alike similarity. 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 and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated 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 ultimately not be a source of medication errors in the usual practice setting, the name is eliminated 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 that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMEPA will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator’s Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC’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 trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. 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)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council’s definition.
5. Medication error staff identify a potential source of medication error within the proposed proprietary name. 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.

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 is awarded approval first has the right to the use the name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then the Division of Medication Error Prevention will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, JCAHO, and ISMP, have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, 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, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Applicant, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, 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 (see limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

2.2 LABEL AND LABELING RISK ASSESSMENT

This section describes the methods and materials used by the DMEPA Staff to conduct a label, labeling, and/or packaging risk assessment (see Section 3, Results). The primary focus of the assessments is to identify and remedy potential sources of medication errors prior to drug approval. 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.⁷

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The container label and carton

⁷ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

labeling communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the United States Pharmacopeia-Institute for Safe Medication Practices Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.⁸

Because the DMEPA staff analyzes reported misuse of drugs, the DMEPA staff is able to use this experience to identify potential errors with all medications similarly packaged, labeled or prescribed. DMEPA uses FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provide recommendations that aim at reducing the risk of medication errors.

DMEPA reviewed the following labels and labeling submitted by the applicant on December 27, 2007. See Appendices I through M for images of the labels and labeling.

- Commercial Container Labels (6.25 mg, 12.5 mg, 25 mg)
- Sample Labels (6.25 mg, 12.5 mg, 25 mg,)
- Sample Blister Labels (12.5 mg, 25 mg)
- Sample Carton Labeling (12.5 mg, 25 mg)
- Package Insert Labeling (no image)

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Databases and information sources

DMEPA conducted a search of the internet, several standard published databases and information sources (see Section 6 References) for existing drug names which sound-alike or look-alike to Nesina to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. In total, nineteen names were identified as having some similarity to the name Nesina.

Nine of the nineteen names were thought to look like Nesina, which include: Mesna, Nesacaine, Mirena, Nescuta, Mesnex, Renova, Mesine, Nasin, and Visine. Four names (Mexsana, (b) (4) Extina, Tasigna) were thought to sound like Nesina. Six names (Nasonex, Nexium, Niaspan, Niacor, Nesina, Lessina) were thought to look and sound similar to Nesina.

3.1.2 CDER Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by the DMEPA staff (see section 3.1.1. above) and noted that additional searches examining names that begin with “R”, “U”, and embodied “ss” in the mid-portion of the name needed to be considered. Even though Nesina is spelled with one “s”, the Expert Panel noted that the proposed name might be phonetically misinterpreted as “Nessina”.

⁸ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

DDMAC had no concerns regarding the proposed name from a promotional perspective and did not offer any additional comments relating to the proposed name.

3.1.3 CDER Prescription Analysis Studies

A total of 37 practitioners responded. One name submitted by a practitioner in the study appears to be a typographical error as it is an exact match to another proposed proprietary name in the prescription study. However, none of the remaining responses overlapped with any existing or proposed drug names. The majority of the misinterpretations occurred in the phonetic prescription study, with the beginning of Nesina being misinterpreted as “Me” or “Ma”, the ending as “seen”, “cin”, or “then”. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 External Name Studies

In the (b) (4) submitted by the Applicant, (b) (4) identified and evaluated a total of five drug names thought to have some potential for confusion with the name Nesina.

Two of the five names, Niacin and Trinessa, were not previously identified in the medication error staff searches or the Expert Panel Discussion. (b) (4) did not believe these drugs names represented a significant risk of confusion or potential for “misprescription” so these names were not evaluated further. The remaining names, Lessina-28, Nexium, and Mesna, were thought by practitioners to look and sound similar to Nesina.

A review of the (b) (4) data noted that the name mesna identified by the medication error staff Search as having look-alike similarity to Nesina was thought by the practitioners consulted in the (b) (4) study to also have some sound-alike similarity.

3.1.5 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Independent searches by the primary Safety Evaluator identified four additional names (Vesicare, Vesprin, (b) (4) and (b) (4) thought to look and/or similar to the proposed proprietary name, Nesina.

Two unique names were identified by (b) (4). As such, a total of 25 names were analyzed to determine if the drug names could be confused with Nesina and if the drug name confusion would likely result in a medication error.

A search of the United States Adopted Name (USAN) stem list on June 23, 2008 identified no USAN stems within the proposed name, Nesina.

All of the identified names were determined to have some orthographic and/or phonetic similarity to Nesina, and thus determined to present some risk for confusion. Failure modes and effects analysis (FMEA) was then applied to determine if the proposed name, Nesina, could potentially be confused with any of the twenty names and lead to medication errors.

The FMEA determined that the name similarity between Nesina and the identified names was unlikely to result in medication errors for 24 of the 25 products for the following reason: Ten names (Nesacaine, Nescuta, Mesnex, Renova, Mexsana, Tassigna, Nexium, Niaspan, Niacin, and TriNessa) lacked convincing orthographic and/or phonetic similarities with Nesina (See Appendix C). Two names, Mesine and Nesina, are marketed outside the United States (See Appendix D). The Nesina found in countries outside the United States appears to have a registered trademark, pending an application. It is unclear what the active ingredient is, however, the Saegis database indicates that it is for diabetes. Since the

*** Note: This is proprietary and confidential information that should not be released to the public.***

(b) (4)
 . One product, (b) (4), was “cancelled” in the USPTO database since 2004 (See Appendix E). Two products (Vesprin, (b) (4)) have either been discontinued and no longer available in generic form, or are products whose proprietary names were found unacceptable or withdrawn (see Appendix F).

For nine of the 25 identified, FMEA determined that medication errors were unlikely because they do not overlap in strength or dose with Nesina and have minimal orthographic and/or phonetic similarity to Nesina (see Appendix G).

The FMEA determined that one name, Lessina-28, was vulnerable to confusion and medication errors due to the orthographic and phonetic similarities in addition to overlapping product characteristics (see Appendix H).

3.2 LABEL AND LABELING RISK ASSESSMENT

Review of the container labels, carton and insert labeling identified several potential sources of medication error.

3.2.1 General Comment

Upon review of the container labels and carton labeling, we note that the applicant uses the colors, (b) (4) and (b) (4), for the 6.25 mg and 25 mg strengths, respectively.

3.2.2 Commercial Container Labels

We are unclear whether the “unit of use” bottles have a Child Resistant Closure (CRC).

3.2.3 Sample Labels

The net quantity statement appears adjacent to the strength statement with equal prominence.

3.2.4 Sample Blister Labels

We note that the strength statement does not identify the strength for each tablet.

We note that a graphic design is present on the label.

3.2.5 Sample Bottle and Blister Carton Labeling

We note that a graphic design is present on the labeling.

3.2.6 Insert Labeling

We note the use of trailing zeroes throughout the insert labeling.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

The results of the Proprietary Name Risk Assessment indicate that the proposed name appears to be vulnerable to name confusion that could lead to medication errors with Lessina-28.

Specifically, the medication error staff identified Lessina-28 as looking and sounding similar to Nesina. Lessina-28 is a monophasic oral contraceptive agent indicated for the prevention of pregnancy. Lessina-28 and Nesina both have five overlapping letters “-esina”, three syllables, and have a similar number of letters (six vs. seven). Moreover, the first letter of each name resembles each other when

written further contributing to their orthographic similarity. The products, Lessina-28 and Nesina, share several characteristics that increase the likelihood of a medication error when used in usual practice settings. These characteristics include: identical frequency of administration (once daily), dosage form (tablet), and route of administration (oral). While the two products do not overlap in product strength (0.02 mg/0.1 mg versus 6.25 mg, 12.5 mg, 25 mg), we believe that the potential for confusion still exists because of the aforementioned overlapping product characteristics in conjunction with the possibility that Nesina's 25 mg strength may inadvertently be confused with "Lessina-28". A prescription written as "Nesina 25 mg – 1 tablet by mouth daily" may be misinterpreted as "Lessina-28 – 1 tablet by mouth daily # 1 month" or "Lessina – 1 tablet by mouth daily # 1 month" or vice versa (see writing sample below). Since the number "25" resembles "28" and vice versa, our concern is that if a prescription is written for "Nesina 25 mg", confusion and subsequent error may result.

The image shows two handwritten prescriptions. The first line reads 'Nesina 25' followed by '1p QD'. The second line reads 'Lessina 28' followed by '1p QD'. The handwriting is in blue ink and is somewhat cursive, illustrating the potential for confusion between the two products due to the similarity in the numbers '25' and '28'.

We do acknowledge that our verbal and written prescription analysis study for Nesina failed to show that the name could be misinterpreted as "Lessina". However, this could be attributed to the strength that was specified in the study (i.e. 6.25 mg) or the sample size, since the sample was small and may not clearly demonstrate what could occur in a larger study. Moreover, we note that the (b) (4) study submitted by the applicant indicated that several of their study respondents (i.e. 10/200 in their pre-abstract association and 5/200 in their post-abstract association) associated Nesina with Lessina. However, they ultimately did not find these two names to be problematic. From their study, it is apparent that there is an association between Nesina and Lessina. Thus, we have concerns that confirmation bias may also contribute to the potential that the healthcare provider will select the wrong product given the similarity of name and overlap of product characteristics.

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, DMEPA believes that these limitations are sufficiently minimized by the use of an Expert Panel, the CDER Prescription Studies that involved 124 CDER practitioners, and, in this case, the data submitted by the applicant from an independent proprietary name risk assessment firm, which included the responses of frontline practitioners.

4.2 LABEL AND LABELING RISK ASSESSMENT

4.2.1 General Comment

The colors used to designate the 6.25 mg and 25 mg strengths, (b) (4) and (b) (4), respectively, are difficult to see because not enough contrast exists between the (b) (4) and (b) (4) colors against the (b) (4) background. To improve the readability of the strength, we suggest using a darker color so that the numbers can be clearly seen.

4.2.2 Commercial Container Labels

It is unclear whether the unit of use package includes a Child Resistant Closure (CRC). Per the Poison Prevention Act, each package should include a child resistant closure if it is intended to be dispensed directly to the patients.

4.2.3 Sample Labels

[REDACTED] (b) (4)

We also note that the net quantity statement appears adjacent to the product strength and in competing prominence. While there is no numerical overlap, the most prominent statements on the labels should be the proprietary and established names and the strength.

4.2.4 Sample Blister Labels and Sample Carton Labeling

[REDACTED] (b) (4)

4.2.5 Insert Labeling

DMEPA notes trailing zeroes are present throughout the insert labeling. The use of trailing terminal zeroes is problematic because decimals are often overlooked resulting in dosing error. As evidenced by our post-marketing surveillance, the use of terminal zeroes could potentially result in a ten-fold medication dose error. Additionally, the use of terminal zeroes in the expression of strength or volume is not in accordance with the General Notices (page 10) of 2004 USP, which states, "...to help minimize the possibility of error in the dispensing and administration of the drugs...the quantity of active ingredient when expressed in whole numbers shall be shown without a decimal point that is followed by a terminal zero." The use of trailing zeroes is specifically listed as a dangerous abbreviation, acronym, or symbol in the 2006 National Patient Safety Goals of The Joint Commission for the Accreditation of Hospitals (JCAHO). Lastly, safety groups such as ISMP also list terminal zeroes on their dangerous abbreviations and dose designations list.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Nesina, appears to be vulnerable to name confusion that could lead to medication errors because of its orthographic similarity to Lessina-28. As such, the medication error staff objects to the use of the proprietary name, Nesina, for this product.

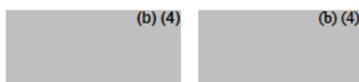
5.1 COMMENTS TO THE DIVISION

We would appreciate feedback of the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy DMEPA on any communication to the sponsor with regard to this review. If you have further questions or need clarifications, please contact Cheryl Milburn, OSE project manager, at 301-796-2084.

5.2 COMMENTS TO THE APPLICANT

The Label and Labeling Risk Assessment findings indicate that the presentation of information and design of the proposed carton and container labels introduces vulnerability to confusion that could lead to medication errors. DMEPA believes the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations below that aim at reducing the risk of medication errors.

1. Revise the presentation of strengths or change the font to improve readability. This may be achieved by outlining the numbers and unit designation with a darker font color or changing the font color so that the numbers are contrasted sufficiently with white background.



2. Since the retail bottles are unit-of-use, ensure that the containers have a Child Resistant Closure (CRC) per the Poison Prevention Act.
3. Please explain whether the word  stamped across the sample label is actually present on the label. We find this presentation problematic as it interferes with the readability of information presented on the label.
4. Ensure that the net quantity statement appears away from the product strength and with less prominence.
5. Revise the Sample Blister Label strength statement so that it reads “XX mg per tablet”.
6. Revise the graphic design so that it does not compete with the prominence of the proprietary and established names.
7. Remove all trailing zeroes throughout the insert labeling.

6 REFERENCES

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

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

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

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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

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

Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in 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. ***Electronic online version of the FDA Orange Book*** (<http://www.fda.gov/cder/ob/default.htm>)

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

Provides information regarding patent and trademarks.

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

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

10. 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.

1. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

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

12. Stat!Ref (www.statref.com)

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)

List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

15. Lexi-Comp (www.lexi.com)

A web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The medication error staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The medication error staff also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has led to medication errors. The medication error staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (i.e. “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the medication error staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, the DMEPA also considers a variety of pronunciations that could occur in the English language.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<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 Upstrokes Downstrokes Cross-strokes	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

		Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	
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

Appendix B:

CDER Prescription Study Responses

Inpatient Prescription	Outpatient Medication Order	Voice Prescription
Nesina	Nesina	Naseena
Nethina	Nesima	Mecina
Nesina	Nesima	Nacina
Nesina	Nesina	Naseena
Nesina	Nesina	Mathena tabs
Nesina	Nesina	Mecina
Nesina	Nesina	Ascina
Nesina	Nesina	Mathena
Nesina	Nesina	
Nesina	Nesina	
Nesina	Nesina	
	Nesina	
	Nesina	
	Nesina	

	Nesina	
	Nesina	

Appendix C: Names that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Nesina
Nesacaine	Look
Nescuta	Look
Mesnex	Look
Renova	Look
Mexsana	Sound
Tasigna	Sound
Nexium	Look and Sound
Niaspan	Look and Sound
Niacin	Look and Sound
TriNessa	Look and Sound

Appendix D: Proprietary names used in Foreign Countries

Name	Similarity to Nesina	Country
Mesine	Look	Ireland
Nesina*	Look and Sound	Norway, Switzerland, China, Japan

* This name has been registered in foreign countries by the same applicant and appears to be for the same indication.

Appendix E: Products whose names have been “cancelled” by the USPTO.

Product name with potential for confusion	Similarity to Nesina
(b) (4)	Sound

Appendix F: Products which have either been discontinued and no longer available in generic form or products whose proposed proprietary names withdrawn.

Product name with potential for confusion	Similarity to Nesina	Status
Vesprin	Look	This product has been discontinued by the manufacturer and is not available in generic form.
Resine	Look and Sound	This product was withdrawn.

Appendix G: Products with no numerical overlap in strength and dose.

Nesina (Alogliptin)		6.25 mg, 12.5 mg, 25 mg	Usual dose: 25 mg daily.
Product name with potential for confusion	Similarity to Nesina	Strength	Usual Dose (if applicable)
Mesna (Mesna)	Look	100 mg/mL Injection 400 mg Tablets	240 mg/m ² as intravenous bolus injection at the time of ifosfamide administration. 480 mg/m ² orally at 2 hours after ifosfamide dose and 480 mg/m ² at 6 hours.
Mirena (Levonorgestrel)	Look	52 mg Intrauterine Device (IUD)	Healthcare practitioner should insert IUD with provided inserter into the uterine cavity within 7 days of the onset of menstruation or immediately after first-trimester abortion.
Nasin (Oxymetazoline)	Look	0.05% Nasal Spray	1 or 2 sprays of 0.05% solution in each nostril twice a day or as required, but no more frequently than

HCl)			every 6 hours.
Visine (Tetrahydrozoline HCl)	Look	0.05% Ophthalmic Solution	Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.
Extina (Ketoconazole)	Sound	2% Topical Foam	Apply to affected areas twice daily for 4 weeks.
Nasonex (Mometasone furoate)	Look and Sound	0.05 mg Nasal Spray	Two sprays in each nostril once a day.
Niacor (Niacin)	Look and Sound	500 mg Tablets	1 gram to 2 grams two or three times a day.
Vesicare (Solifenacin Succinate)	Look	5 mg, 10 mg Tablets	5 mg to 10 mg once a day.

(b) (4)

*** Note: This is proprietary and confidential information that should not be released to the public. ***

Appendix H: Products identified as resulting in medication errors

Nesina (Alogliptin)	6.25 mg, 12.5 mg, 25 mg	Usual dose: 25 mg daily.
Failure Mode: Name confusion	Causes (could be multiple)	Effects
Lessina-28	<p>Orthographic and phonetic similarity (Both names contain the letters “-esina”. “-essina” vs. “-esina”) and they share a similar number of letters (seven vs. six) and syllables (three). When pronounced, the first letters, “L” versus “N”, are negligible.</p> <p>Both share the same route of administration (oral), dosage form (tablet), and frequency of administration (once daily).</p>	<p>When written and spoken, the names appear and sound similar. The added similarity of the overlapping dosage form, route of administration, and frequency will likely result in a medication error.</p> <p>Additionally, while the two products do not overlap in product strength (0.02 mg/0.1 mg versus 6.25 mg, 12.5 mg, 25 mg), we believe that the potential for confusion still exists because of the aforementioned overlapping product characteristics in conjunction with the possibility that Nesina’s 25 mg strength may inadvertently be confused with “Lessina-28”. A prescription written as “Nesina 25 mg – 1 tablet by mouth daily” may be misinterpreted as “Lessina-28 – 1 tablet by mouth daily # 1 month” or “Lessina – 1 tablet by mouth daily # 1 month” or vice versa (see writing sample below). Since the number “25” resembles “28” and vice versa, our concern is that if a prescription is written for “Nesina 25 mg”, confusion and subsequent error may result.</p> <p>Moreover, unfamiliarity with the newly marketed drug name at the product launch will likely enhance the risk for medication errors, as confirmation bias related to the similarity in name and product characteristics contributes to the potential a caregiver will misinterpret the prescription.</p>

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/s/

Jinhee Jahng
9/15/2008 03:37:50 PM
DRUG SAFETY OFFICE REVIEWER

Kellie Taylor
9/16/2008 05:02:44 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
9/23/2008 04:40:08 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
9/23/2008 04:47:05 PM
DRUG SAFETY OFFICE REVIEWER