# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**202057Orig1s000**

# PROPRIETARY NAME REVIEW(S)

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

# Proprietary Name Review--Final

| | |
|---|---|
| Date: | June 11, 2012 |
| Acting Team Leader: | Jamie Wilkins Parker, Pharm.D.<br>Division of Medication Error Prevention and Analysis |
| Drug Name(s) and Strength(s): | Vascepa (Icosapent Ethyl) Capsules, 1 gram |
| Application Type/Number: | NDA 202057 |
| Applicant/sponsor: | Amarin Pharma, Inc. |
| OSE RCM #: | 2012-916 |

*** 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, Vascepa 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, *Vascepa*, acceptable in OSE Review 2011-3599 dated December 16, 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 2011-3599. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded four new names (Vicoprin, Rezpias, (b) (4), and Vascana***), thought to look or sound similar to Vascepa 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 Vicoprin, Rezipas, (b) (4) or Vascana*** and lead to medication errors. This analysis determined that the name similarity between Vascepa 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, as of June 11, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on April 19, 2012 and had no concerns regarding the proposed name from a promotional perspective.

## 3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053.

# 4 REFERENCES


**1. OSE Reviews**

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

**Appendix 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 Vacscepa | Failure Preventions |
|---|---|---|---|
| Vicoprin | Aspirin/Hydrocodone | Orthographic | Proprietary name for ANDA 086333 which is discontinued and application withdrawn, FR effective 10/30/1987 with no available therapeutic equivalents. |
| Rezipas | Aminosalicylic Acid Resin Complex | Orthographic | Proprietary name for NDA 009052, which is discontinued and application withdrawn, FR effective 9/13/2000. No therapeutic equivalents currently exist in the market. |
| | | | (b) (4) |

**Appendix B: FMEA Table**

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Vascana*** (Nitroglycerin in a Topical Amphi-Matrix) (Current application status- Complete Response 10/24/2008)**<br>-0.9% topical gel to deliver 0.5 grams of gel (4.5 mg of nitroglycerin)<br>-Apply the entire contents of one pouch to the tops and sides of the affected fingers of both hands in anticipation of a Raynaud's attack or within 5 minutes after onset of a Raynaud's attack | **Orthographic name similarity**<br>- Both names begin with the letter string Vasc, and end with the letter a.<br>**Product characteristics**<br>-Strength (both are single strength products) | **Product characteristic differences**<br>-Frequency (once or twice daily vs. use as directed or apply the contents of one package in anticipation of an attack or 5 minutes after onset of an attack )<br>-Dose (1 or 2 capsules vs. one package or use as directed) |

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/s/

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JAMIE C WILKINS PARKER
06/11/2012

**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

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|---|---|
| Date: | December 16, 2011 |
| Reviewer(s): | Jamie Wilkins Parker, Pharm.D.<br>Division of Medication Error Prevention and Analysis |
| Team Leader | Carlos Mena-Grillasca, RPh<br>Division of Medication Error Prevention and Analysis |
| Division Director | Carol A. Holquist, RPh<br>Division of Medication Error Prevention and Analysis |
| Drug Name(s)<br>and Strength(s): | Vascepa (Icosapent Ethyl) Capsules, 1 gram |
| Application Type/Number: | NDA 202057 |
| Applicant/Sponsor: | Amarin Pharma, Inc. |
| OSE RCM #: | 2011-3559 |

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# 1 INTRODUCTION

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

## 1.1 REGULATORY HISTORY

The Applicant submitted the proprietary name request for Vascepa Capsules (NDA 202057) on September 26, 2011.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the September 26, 2011 proprietary name submission.

- Established Name: Icosapent Ethyl
- Indication of Use: Adjunct to diet to reduce triglyceride (b) (4) in adult patients with very high (≥500 mg/dL) triglycerides
- Route of administration: Oral
- Dosage form: Capsule
- Strength: 1 gram
- Dose: (b) (4) 2 capsules twice daily, (b) (4) (b) (4)
- How Supplied: 4 capsule physician sample pack, 120 capsule trade bottle
- Storage: 25C (77F) with excursions permitted to 15C-30C(58-86F)
- Container and Closure systems: 120 capsules in a (b) (4) HDPE bottle, (b) (4); 4 capsules in a (b) (4) HDPE bottle. (b) (4)

# 2. RESULTS

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

## 2.1 PROMOTIONAL ASSESSMENT

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

## 2.2 SAFETY ASSESSMENT

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

### *2.2.1 United States Adopted Names (USAN) SEARCH*

On December 9, 2011 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

### *2.2.2 Components of the Proposed Proprietary Name*

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

### *2.2.3 FDA Name Simulation Studies*

*Forty-one* practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound or look similar to any currently marketed products. Eleven of the thirteen inpatient samples were interpreted correctly, four of the seventeen outpatient samples were interpreted correctly, and nine of the eleven voice samples were interpreted as something phonetically similar to Vascepa. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### *2.2.4 Comments from Other Review Disciplines*

In response to the OSE, November 8, 201 e-mail, the Division of Metabolic and Endocrine Products (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

### *2.2.5 Failure Mode and Effects Analysis of Similar Names*

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

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

| **Look Similar** | | **Sound Similar** | | **Look and Sound Similar** | |
|---|---|---|---|---|---|
| ***Name*** | ***Source*** | ***Name*** | ***Source*** | ***Name*** | ***Source*** |
| Veregen | FDA | Zebeta | FDA | Vaniqa | FDA |
| Vesprin | FDA | Varicella | FDA | Vasocon | FDA |
| Naropin | FDA | | | Zavesca | FDA |
| Neumega | FDA | | | Maxepa | DSI |

| Look Similar | | Sound Similar | | Look and Sound Similar | |
|---|---|---|---|---|---|
| Viroxyn | FDA | | | Parcopa | DSI |
| Vasaka | FDA | | | Valcyte | DSI |
| Vasoxyl | FDA | | | Vapo-Iso | DSI |
| Vezepra | FDA | | | Vepesid | DSI |
| Vascugel | FDA | | | Versapen | DSI |
| Urpsias | FDA | | | Visipaque | DSI |
| Vasceze | FDA | | | Vascor | Both |
| Vasoclear | FDA | | | Vaseretic | Both |
| Vitaped | FDA | | | Vasocidin | Both |
| (b) (4) | FDA | | | Vasolex | Both |
| Vospire | FDA | | | Vasopressin | Both |
| Vascer | FDA | | | Vasotec | Both |
| Vascon | FDA | | | Vesicare | Both |
| Vasoflex | FDA | | | Viagra | Both |
| Vasocine | FDA | | | Viracept | Both |
| Vascoray | FDA | | | | |
| Vidaza | FDA | | | | |
| Nascobal | FDA | | | | |
| Vasovist | FDA | | | | |
| Reserpine | FDA | | | | |
| Vescopam | FDA | | | | |
| Invega | FDA | | | | |

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

### *2.2.6 Communication of DMEPA's Final Decision to Other Disciplines*

DMEPA communicated our findings to the Division of Metabolic and Endocrine Products via e-mail on December 8, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolic and Endocrine Products on December 9, 2011, they stated "no objection" to DMEPA's evaluation.

## 2 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

### 2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Vascepa, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your September 26, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

## 3 REFERENCES


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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book Pharmacy's Fundamental Reference***

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

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

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

15. ***Medical Abbreviations Book***

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

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

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

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

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

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

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

***19. Dogpile (www.dogpile.com)***

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

## APPENDICES

### Appendix A

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

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

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

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** | | |
|---|---|---|---|
| | *Potential Causes of Drug Name Similarity* | *Attributes Examined to Identify Similar Drug Names* | *Potential Effects* |
| Look-alike | Similar spelling | Identical prefix<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name/Similar shape<br>Upstrokes<br>Down strokes<br>Cross-strokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

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

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

### 1. Database and Information Sources

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

### 2. Expert Panel Discussion

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

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

### 3. FDA Prescription Simulation Studies

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

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

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

### 4. Comments from Other Review Disciplines

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

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

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

### 5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Appendix B:** Letters with Possible Orthographic or Phonetic Misinterpretation

| Letters in Name, Vascepa | Scripted May Appear as | Spoken May Be Interpreted as |
|---|---|---|
| V | U, N, Z, r, u, n, r, c, | F, B |
| a | Any vowel, er | Any vowel |
| s | r, a, n, g, e | x, c |
| c | a, e, l, i | z, k, s |
| e | Any vowel, l | Any vowel |
| p | g, j, l, q | b |
| a | Any vowel, er | Any vowel |

**Appendix C:** Prescription Simulation Samples and Results

**Figure 1. Vascepa Study (Conducted on October 7, 2011)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>Vascepa 1 capsule PO BID<br><br>Outpatient Prescription:<br>Vascepa<br>2 caps po bid<br>#120 | Vascepa<br>2 capsules PO BID<br>#120 |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

85 People Received Study

41 People Responded

Study Name: Vascepa

| INPATIENT | STRENGTH | VOICE | STRENGTH | OUTPATIENT | STRENGTH |
|---|---|---|---|---|---|
| VASCEPA | | BASIMBA | | BASCYSER | |
| VASCEPA | | VASEMBA | | VASCEPA | |
| VASCEPA | 1 cap | VASEPA | | VASCEPA | |
| VASCEPA | | VASEPA | | VASCEPA | |
| VASCEPA | 1 cap | VASEPA | | VASCEPA | |
| VASCEPA | | VASEPA | | VASCEPER | |
| VASCEPA | | VASEPA | | VASCEPER | none |
| VASCEPA | | VASEPA | | VASCIPA | |
| VASCEPA | none | VASEPPA | | VASCIPA | None |
| VASCEPA | | VASEPPA | | VASCIPA | |
| VASCEPA | na | VESEPA | | VASCIPA | |
| VASCEPH | one cap | | | VASCIPA | |
| VASCEPH | 1 capsule | | | VASCIPER | |
| | | | | VASCIPER | none |
| | | | | VASCYPER | None given |
| | | | | VASCYSER | |
| | | | | VASCYSER | none given |

**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 Vascepa | Failure preventions |
|---|---|---|---|
| Vesprin | Trifluprom azine | Orthographic | Product discontinued, application withdrawn FR notification 3/2/1994, 5/29/2002, and 4/4/2005. Preliminary drug use data indicates no prescribing of the name Vesprin. |
| Vasaka | Malabar Nut | Orthographic | Proprietary name for the Malabar Nut herb. Preliminary drug use data indicates no prescribing of the name Vasaka. |
| Vasoxyl | Methoxamine Hydrochloride | Orthographic | Product discontinued, application withdrawn FR notification 9/2001. Preliminary drug use data indicates no prescribing of the name Vasoxyl. |
| Vascugel | Allogeneic human aortic endothelial cells cultured in a porcine gelatin matrix | Orthographic | Orphan product with no current open applications. |
| Vasoclear | Naphazoline 0.02% ophthalmic solution | Orthographic | Product discontinued, preliminary drug use data indicates no prescribing of the name Vasoclear. |
| Vitaped | Pediatric Strength Multivitamin | Orthographic | Product discontinued with no generic equivalents, application withdrawn FR notification 6/16/2006. Preliminary drug use data indicates no prescribing of the name Vitaped. |
| [redacted] | | | (b) (4) |
| Vascer | Pentoxifylline | Orthographic | International name used in Brazil. |
| Vascon | Norepinephrine | Orthographic | International name used in India. |
| Vasovist | gadofosveset | Orthographic | International name, used in multiple countries in Europe. |
| Vescopam | Diazepam | Orthographic | International name used in Thailand. |
| Vasocon | Naphazoline | Orthographic | Name discontinued, application withdrawn FR notification 6/11/2007. Preliminary use data indicates very low prescribing of the name, Vasocon. |

| | | | |
|---|---|---|---|
| Varicella | Name for the virus that causes the disease commonly known as "chicken pox" | Phonetic | Product lacks convincing phonetic similarity to the name Vascepa. |
| Valcyte | Valganciclovir | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vaseretic | Enalapril/HCTZ | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vezepra | Pitavastatin | Orthographic | Trade name abandoned 5/18/2009 according to USPTO; name only used in Europe and Australia |
| Vasocidin | Prednisolone/Sulfacetamide | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Neumega | Oprelvekin | Orthographic | Orphan drug with two open IND research applications |
| Reserpine | n/a | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Visipaque | Iodixanol | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Zebeta | Bisoprolol | Phonetic | Product lacks convincing phonetic similarity to the name, Vascepa. |
| Vasoflex | Prazosin (in Bosnia, Croatia, and Slovenia), multivitamin (in the US) | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vasocine | Sulfacetamide and Prednisolone Opthalmic Ointment | Orthographic | Unable to locate product in any database except Walgreens. |
| Vasopressin | n/a | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vascoray | Iothalamate | Orthographic | Name discontinued, application withdrawn FR notification 3/13/2009. Preliminary use data indicates no prescribing of the name Vascoray. |
| Vapo-Iso | Isoproterenol | Orthographic | Name discontinued, application withdrawn FR notification 3/2/1994. Preliminary use data indicates no prescribing of the name Vapo-Iso. |
| Versapen | Hetacillin | Orthographic | Name discontinued, application withdrawn FR notification 11/5/1992. ANDA applications withdrawn 12/17/1990 and 2/2/2001. Preliminary use data indicates no prescribing of the name Versapen. |

| | | | |
|---|---|---|---|
| Vepesid | Etoposide | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vascor | Bepridil | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vasotec | Enalapril, Enalaprilat | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Vesicare | Solifenacin | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |
| Invega | Paliperidone | Orthographic | Product lacks convincing orthographic similarity to the name, Vascepa. |

**Appendix E:** Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Veregen (Sinecatechins)**<br>- 15% topical ointment<br>-Apply a 0.5 cm strand to each wart three times daily | **Orthographic name similarity**<br>- Both names are similarly shaped and contain seven letters<br>**Product characteristics**<br>-Strength (both are single strength products) | **Product characteristic differences**<br>-Frequency (once or twice daily vs. three times daily or use as directed)<br>-Dose (1 or 2 capsules vs. 0.5 cm strand or use as directed)<br>-Dosage Form (Capsule vs. topical ointment)<br>-Route of administration (oral vs. topical) |
| **Naropin (Ropivacaine)**<br>- 0.2%, 0.5%, 0.75%, 1% solution for injection<br>- 1-100 mL given in incremental doses, or up to 15 mL per hour for continuous nerve blocks | **Orthographic name similarity**<br>-Both names are similarly shaped and contain seven letters | **Product characteristic differences**<br>-Frequency of administration (once or twice daily vs. incremental or continuous dosing)<br>-Strength (single strength product which would not be required to be written on a prescription, none of the strengths overlap vs. 0.2%, 0.5%, 0.75%, or 1%)<br>-Route of administration (oral vs. epidural or nerve block where a region/location would need to be specified)<br>-Use environment (home vs. inpatient/surgical) |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Viroxyn (benzalkonium chloride and isopropyl alcohol)**<br>-0.13% solution<br>-One single application to affected area, treat new lesions with a new vial | **Orthographic name similarity**<br>- Both names are similarly shaped, and contain a downstroke in the sixth position<br>**Product characteristics**<br>-Strength (both are single strength products) | **Product Characteristic Differences**<br>-Frequency (once or twice daily vs. single application)<br>-Dosage Form (capsule vs. solution)<br>-Route of administration (oral vs. topical) |
| **Urispas (flavoxate)**<br>-100 mg tablet<br>- 100-200 mg (1-2 tablets) by mouth 3-4 times daily depending on tolerance and response | **Orthographic name similarity**<br>-Both names begin with similarly shaped letters (V vs. U), contain downstrokes in the second half of the name, and contain seven letters<br>**Product characteristics**<br>-Route of administration (oral)<br>-Dose (1-2 tablets/capsules)<br>- Strength (both are single strength products) | **Product Characteristic differences**<br>-Frequency (once or twice daily vs. three to four times daily)<br>-Preliminary drug use data indicates low prescribing of the name, Urispas. |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Vasceze (Sodium Chloride or Heparin Sodium)**<br>-Product is the proprietary name for two separate products<br>-Heparin Sodium 100 units/mL (Heparin Lock Flush)<br>-0.9% Sodium Chloride 5 mL<br>-Used as an intravenous line flush | **Orthographic name similarity**<br>-Both names contain seven letters, a downstroke in the sixth position, and 5 of the seven letters in the names overlap<br>**Product characteristics**<br>-Strength (both are single strength products)<br>-Frequency (both products can be administered once or twice daily) | **Product Characteristic differences**<br>-The molecular entity will need to be specified on a prescription for Vasceze, therefore differentiating if from a prescription for Vascepa, which does not require a molecular modifier.<br>-Preliminary drug use data indicates no prescribing of the name, Vasceze. |
| **Vospire (Albuterol extended-release)**<br>**-Note this product was searched as Vospire, not Vospire ER, and only exists with the modifier**<br>-4 mg, 8 mg extended-release tablets<br>- 4-8 mg by mouth every 12 hours, not to exceed 32 mg per day | **Orthographic name similarity**<br>-Both names begin with the letter V, and contain a downstroke<br>**Product characteristics**<br>-Route of administration (oral)<br>-Frequency (both can be dosed every 12 hours) | **Product Characteristic differences**<br>-Strength (single strength which would not be required to be written on a prescription, none of the strengths overlap vs. 4 mg and 8 mg tablets) |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Vidaza (azacitadine)**<br>-100 mg powder for injection<br>-75 mg/$m^2$ subcutaneously or intravenously once daily for 7 days every 4 weeks. Intravenous dose may be increased to 100 mg/$m^2$ same regimen, if no response. Average adult dose (based upon BSA of 1.73 $m^2$) would be 129.75 mg | **Orthographic name similarity**<br>-Both names begin with the letter V and contain a downstroke<br>**Product characteristics**<br>-Strength (single strength)<br>-Frequency (both can be dosed once daily) | **Orthographic Differences**<br>-Vascepa does not contain any upstrokes, whereas Vidaza contains an upstroke in the third position.<br>**Product Characteristic differences**<br>-Route of administration (oral vs. subcutaneous or intravenous)<br>-Dose (1-2 capsules vs. mg) |
| **Nascobal (Cyanocobalamin)**<br>-500 mcg/0.1 mL nasal gel or spray<br>-500 mcg (one spray) into one nostril intranasally once weekly | **Orthographic name similarity**<br>-Both names begin with similarly shaped letter strings (Vas vs. Nas)<br>**Product characteristics**<br>-Strength (single strength) | **Orthographic Differences**<br>-Vascepa does not contain any upstrokes, whereas Nascobal contains upstrokes in the sixth and eighth positions.<br>**Product Characteristic differences**<br>-Route of administration (oral vs. intranasal)<br>-Dose (1-2 capsules vs. one spray)<br>-Dosage Form (capsule vs. spray or gel)<br>-Frequency (once or twice daily vs. once weekly) |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Vaniqa (eflornithine)**<br>-13.9% topical cream<br>-apply a thin layer twice daily (at least 8 hours apart) to affected areas, do not wash area for at least 4 hours | **Orthographic name similarity**<br>-Both names are similarly shaped<br>**Phonetic similarities**<br>-Both names begin with the letter string 'Va', and end with similar sounding letter strings (pa vs. qa)<br>**Product characteristics**<br>-Strength (single strength)<br>-Frequency (both products can be administered twice daily) | **Orthographic Differences**<br>-Vascepa contains a downstroke in the 6th position whereas Vaniqa contains a downstroke in the fifth. The letters preceding the downstroke in the name Vascepa confer a longer shape to the name, therefore making Vascepa appear longer when scripted.<br>**Product Characteristic differences**<br>-Dose (1-2 capsules vs. apply a thin layer or use as directed)<br>-Dosage Form (oral capsule vs. topical cream)<br>-Route of administration (oral vs. topical) |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** [redacted] | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Zavesca (miglustat)**<br>-100 mg capsule<br>-100 mg three times daily at regular intervals | **Phonetic name similarity**<br>-Both names end with similar letter strings (epa vs. esca)<br>**Product characteristics**<br>-Strength (single strength)<br>-Route of administration (oral) | **Phonetic Differences**<br>- When pronounced correctly, the e in Vascepa should be the 'long' e vowel sound, whereas the e in Zavesca is the 'short' e vowel sound. If the e in Vascepa were to be pronounced with the short 'e' sound, the c in Zavesca allows for a distinctive, hard consonant sound to differentiate the names from one another. The initial 'v' sound in Vascepa is labio-dental fricative, whereas the initial 'z' sound in Zavesca is alveolar affricate<br>**Product Characteristic differences**<br>-Frequency (once or twice daily vs. three times daily)<br>-Preliminary drug use data indicates no prescribing of the name, Zavesca. |
| **Maxepa (Fish Oil)**<br>-1 gram capsules<br>-1 gram by mouth 2-3 times daily | **Orthographic similarity**<br>-Both names end in the letter string 'epa'<br>**Phonetic name similarity**<br>-Both names end with the same letter string<br>**Product characteristics**<br>-Strength (1 gram)<br>-Route of administration (oral)<br>-Frequency (both can be dosed 2 times daily) | **Orthographic Differences**<br>-The letter string 'Vas' appears different from the letter string 'Max' when scripted<br>**Phonetic Differences**<br>-The letter string 'Vas' sounds different from the letter string 'Max' when pronounced. The initial 'v' sound in Vascepa is labio-dental fricative, whereas the initial 'm' sound in Maxepa is bilabial nasal.<br>-Preliminary use data indicates no prescribing of the name, Maxepa. |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** [redacted] | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Parcopa (Carbidopa/Levodopa)**<br>-10 mg/100 mg,<br>25 mg/100 mg,<br>25 mg/200 mg tablets<br>-50-200 mg Carbidopa per day/<br>400-2000 mg Levodopa per day in 2-4 divided doses | **Orthographic similaritiy**<br>-Both names end in similarly shaped letter strings (cepa vs. copa)<br>**Product characteristics**<br>-Route of administration (oral)<br>-Frequency (both can be dosed 2 times daily) | **Product characteristics**<br>-Strength (Single strength product which would not be required to be written on a prescription, none of the strengths overlap vs.<br>10 mg/100 mg, 25 mg/100 mg, or 25 mg/200 mg) |
| **Viagra (Sildenafil)**<br>-25 mg, 50 mg, 100 mg tablets<br>-1 tablet (25-100 mg) 30-60 minutes prior to intercourse | **Orthographic similarities**<br>-Both names begin with the letter V, and contain a downstroke<br>**Product characteristics**<br>-Route of administration (oral) | **Orthographic differences**<br>-Vascepa contains seven letters whereas Viagra contains six. The downstroke in Vascepa occurs in the sixth position whereas the downstroke in Viagra occurs in the fourth position, therefore giving the names different shapes when scripted, as well as Vascepa appearing longer when scripted.<br>**Product characteristic differences**<br>-Strength (single strength product which would not be required to be written on a prescription, none of the strengths overlap vs. 25 mg, 50 mg, or 100 mg)<br>-Frequency (once or twice daily vs. 30-60 minutes prior to intercourse or use as directed) |

| **Proposed name: Vascepa (icosapent ethyl)**<br>**Strength(s) and Dosage Form: 1 gram capsules**<br>**Usual dose: (b) (4) two capsules twice daily, (b) (4)** (b) (4) | **Causes of Failure Mode Resulting in Medication Error: Incorrect Product Ordered/ Selected/Dispensed or Administered Because of Name confusion** | **Prevention of Failure Mode: Orthographic/Phonetic/Product Characteristic Differences** |
|---|---|---|
| **Viracept (Nelfinavir)**<br>-250 mg, 650 mg tablets, 50 mg/gram oral powder<br>-1250 mg twice daily or 750 mg three times daily with a meal | **Orthographic similarities**<br>-Both names begin with the letter V, and contain a downstroke 'p'<br>Product characteristics<br>-Route of administration (oral)<br>-Frequency (both can be dosed twice daily) | **Orthographic differences**<br>Vascepa contains seven letters whereas Viracept contains eight, as well as an upstroke 't' and therefore appears longer and is shaped differently when scripted.<br>**Product characteristic differences**<br>-Strength (single strength product which would not be required to be written on a prescription, none of the strengths overlap vs. 250 mg, 650 mg or oral powder) |

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/s/

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JAMIE C WILKINS PARKER
12/16/2011

CAROL A HOLQUIST
12/19/2011