

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**022416Orig1s000**

**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 23, 2013

Reviewer: Julie Neshiewat, PharmD  
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS  
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Aptiom (Eslicarbazepine Acetate) Tablets  
200 mg, 400 mg, 600 mg, 800 mg

Application Type/Number: NDA 022416

Applicant/Sponsor: Sunovion Pharmaceuticals

OSE RCM #: 2013-1932

\*\*\* 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, Aptiom, 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. DMEPA previously reviewed the proposed proprietary names Stedesa<sup>1,2</sup> and (b) (4)<sup>3</sup> for this Application.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the August 22, 2013 proprietary name submission.

- Active Ingredient: Eslicarbazepine Acetate
- Indication of Use: Adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years and older
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 200 mg, 400 mg, 600 mg, 800 mg
- Dose and Frequency: Initiate with a once daily dose of 400 mg for one week; daily dosing may be increased at increments of 400 mg at approximately weekly intervals to a maximum recommended dose of 1200 mg once daily. The usual maintenance dose is 800 mg once daily. For some patients, therapy may be initiated at 800 mg once daily if the need for seizure control outweighs a potentially increased risk of adverse events during initiation
  - Patients with a creatinine clearance below 50 mL/min: Initiate with a once daily dose of 200 mg for two weeks followed by a once daily dose of 400 mg. The dose may be increased to a maximum of 600 mg.
- How Supplied:
  - Retail
    - 200 mg (scored): 30-count bottles
    - 400 mg: 30-count bottles
    - 600 mg (scored): 60-count and 90-count bottles
    - 800 mg (scored): 30-count and 90-count bottles

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<sup>1</sup> Neshiewat J. Stedesa Proprietary Name Teleconference (NDA 022416). Silver Spring (MD): Food and Drug Administration, Division of Medication Error Prevention and Analysis (US); 2013 May 1.

<sup>2</sup> Joyce K. Withdrawal of Request for Proprietary Name Review, Stedesa (Eslicarbazepine Acetate), NDA 022416/SN0088. Marlborough (MA): Sunovion Pharmaceuticals, Inc. 2013 May 9.

<sup>3</sup>

(b) (4)

- Professional sample
  - 400 mg: 7-count blister wallet (carton of 4 blister wallets)
  - 600 mg (scored): 7-count blister wallet (carton of 4 blister wallets)
  - 800 mg (scored): 7-count blister wallet (carton of 4 blister wallets)
  - Starter Pack 400 mg (scored) and 800 mg (scored): 14-count blister wallet; 7-count of each strength (carton of 4 blister wallets)
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
- Container and Closure Systems: High-density polyethylene (HDPE) bottles; (b) (4) blisters and imprinted aluminum foil lidding

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Neurology Products (DNP) 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*

There is no USAN stem present in the proposed proprietary name.<sup>4</sup>

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

The Applicant indicated in their submission that the proposed name, Aptiom, has no intended meaning. This proprietary name is comprised of a single word that does not contain any components such as a modifier, route of administration, dosage form, etc.

#### 2.2.3 *FDA Name Simulation Studies*

Sixty-nine practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. One practitioner commented that it is not clear if the first letter is an 'S' or an 'I,' but if it is an 'I,' it looks like Isoptin at first glance. The written prescription studies indicate that the first letter 'A' can be misinterpreted as an 'S' or 'I,'

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<sup>4</sup> USAN stem list searched September 16, 2013.

the letter ‘i’ can be misinterpreted as an ‘r,’ and the letter ‘m’ can be misinterpreted as an ‘n.’ The verbal prescription study indicates that ‘pt’ can be misheard as an ‘ct’ or ‘bt’ We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results of the verbal and written prescription studies.

**2.2.4 Comments from Other Review Disciplines at Initial Review**

In response to the OSE, September 6, 2013 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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

The potential letter and letter string variations listed in Appendix B were used to search for names with possible orthographic and phonetic similarity to the proposed proprietary name, Aptiom (see Table 1).

Our analysis of the 36 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 36 names will not pose a risk for confusion as described in Appendices D through E.

<b>Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and FDA Prescription Studies)</b>					
<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Aglicem	FDA	Antizol	FDA	Apitoxin	FDA
Optruma	FDA	Aplisol	FDA	Optimine	FDA
Apton	FDA	Apriso	FDA	Hytrin	FDA
Optive	FDA	Cytoxan	FDA	Systane	FDA
(b) (4)	FDA	(b) (4)	FDA	Opti-one	FDA
(b) (4)	FDA	Optura <sup>***</sup>	FDA	Aptein	FDA
Aptivus	FDA	(b) (4)	FDA	Optase	FDA
Optivar	FDA	(b) (4)	FDA	Optics Eye Wash	FDA
Optima 100	FDA	Isoptin	FDA	Actron	FDA

<sup>\*\*\*</sup> This document contains proprietary and confidential information that should not be released to the public.

<b>Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and FDA Prescription Studies)</b>					
<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Ceptaz	FDA	(b) (4)	FDA		
<b>Look and Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Optisone	FDA	Epzicom	FDA	Optimum	FDA
Opticrom	FDA	Optison	FDA	Optium	FDA
Opium	FDA				

### **2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review**

DMEPA communicated our findings to the Division of Neurology Product via e-mail on October 11, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Product on October 11, 2013, they stated the proposed proprietary name, Aptiom, was the name of the company’s subsidiary that acquired Sepracor, who owns Eslicarbazepine Acetate. However, our further research determined that when Sepracor was merged with Dainippon Sumitomo Pharma America, the company was named Sunovion and not Aptiom. Therefore, the use of Aptiom as the proposed proprietary name for this product does not raise a safety concern.

## **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 Ermias Zerislassie, OSE project manager, at 301-796-0097.

### **3.1 COMMENTS TO THE APPLICANT**

We have completed our review of Aptiom and have concluded that it is acceptable. If any of the proposed product characteristics as stated in your August 22, 2013 submission are altered, the name must be resubmitted for review.

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## 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](http://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. ***Natural Medicines Comprehensive Databases*** ([www.naturaldatabase.com](http://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.
10. ***Access Medicine*** ([www.accessmedicine.com](http://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.
11. ***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.
12. ***Red Book*** ([www.thomsonhc.com/home/dispatch](http://www.thomsonhc.com/home/dispatch))  
Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.
13. ***Lexi-Comp*** ([www.lexi.com](http://www.lexi.com))  
Lexi-Comp is a web-based searchable version of the Drug Information Handbook.
14. ***Medical Abbreviations*** ([www.medilexicon.com](http://www.medilexicon.com))  
Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.
15. ***CVS/Pharmacy*** ([www.CVS.com](http://www.CVS.com))  
This database contains commonly used over the counter products not usually identified in other databases.
16. ***Walgreens*** ([www.walgreens.com](http://www.walgreens.com))  
This database contains commonly used over the counter products not usually identified in other databases.
17. ***Rx List*** ([www.rxlist.com](http://www.rxlist.com))  
RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.
18. ***Dogpile*** ([www.dogpile.com](http://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.

**19. 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.<sup>5</sup>

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

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

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

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<sup>5</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>6</sup>

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).

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<sup>6</sup> 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.

<b>Type of Similarity</b>	<b>Considerations when Searching the Databases</b>		
	<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"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	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"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
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"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

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.<sup>7</sup> 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

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<sup>7</sup> 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

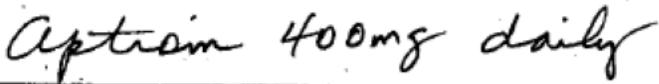
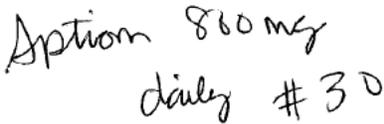
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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, Aptiom	Scripted May Appear as	Spoken May Be Interpreted as
Upper case 'A'	Fl, H, ce, s, T, D, O, I	Any vowel
Lower case 'a'	el, ci, cl, d, o, u	Any vowel
Lower case 'p'	yn, ys, g, j, q	b, c, f
Lower case 't'	f, x, l, b	d
Lower case 'i'	e, l, r	Any vowel
Lower case 'o'	a, c, e, u, s	Any vowel
Lower case 'm'	m, mm, n, v, w, wi, vi, onc, z, rv, rr, nr, in, ru	n
Letter strings		
Lower case 'ti'	h	

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

**Figure 1. Study (Conducted on September 3, 2013)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Aptiom 800 mg Take one daily Dispense # 30</p>
<p><u>Outpatient Prescription:</u></p> 	

**Study Name: Aptiom**

191 People Received Study

69 People Responded

<b>Total</b>	<b>24</b>	<b>26</b>	<b>19</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
ABTEUM	0	1	0	1
ABTIOM	0	1	0	1
ACTIAM	0	2	0	2
ACTIOM	0	1	0	1
ACTIUM	0	2	0	2
AFTIOM	0	1	0	1
APIUM	0	1	0	1
APTEIUM	0	1	0	1
APTIAN	0	0	1	1
APTIOM	10	11	5	26
APTION	5	1	0	6
APTISM	0	0	2	2
APTIUM	0	4	0	4
APTRAIN	0	0	2	2
APTRAM	0	0	2	2
APTRIM	0	0	1	1
APTRIOM	0	0	1	1
APTROIN	0	0	1	1
APTRROM	0	0	4	4
IPTIOM	1	0	0	1
IPTION	1	0	0	1
OPTIOM	1	0	0	1
SPTIOM	3	0	0	3
SPTION	3	0	0	3

**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 Aptiom	Failure preventions
1.	Aglicem	Tolbutamide	Look alike	International product marketed in Spain.
2.	Opturma	Raloxifene	Look alike	International product marketed in several countries other than the U.S.
3.	Apton	Pantoprazole	Look alike	International product marketed in Portugal.
4.	Optive	Carboxymethylcellulose	Look alike	International product marketed in Malaysia.
5.	Antizol	Fomepizole	Look alike	The pair has sufficient orthographic differences.
6.	Aplisol	Tuberculin Purified Protein Derivative	Look alike	The pair has sufficient orthographic differences.
7.	Apriso	Mesalamine	Look alike	The pair has sufficient orthographic differences.
8.	Cytoxan	Cyclophosphamide	Look alike	The pair has sufficient orthographic differences.
9.	Apitoxin	Bee venom	Look alike	The pair has sufficient orthographic differences.
10.	Optimine	Azatadine Maleate	Look alike	The pair has sufficient orthographic differences.
11.	Hytrin	Terazosin	Look alike	The pair has sufficient orthographic differences.
12.	Systane	Artificial Tears	Look alike	The pair has sufficient orthographic differences.
13.	(b) (4)	(b) (4)	Look alike	The pair has sufficient orthographic differences.
14.	(b) (4)	Ceftaroline Fosamil	Look alike	Alternative name for a proposed product that was not formally submitted for review. Product approved under new proprietary name Teflaro.

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

15.	(b) (4)	(b) (4)	Look alike	(b) (4)
16.	Optura ***	Besifloxacin Hydrochloride	Look alike	Proposed proprietary name found unacceptable by DMEPA (OSE # 2008-415). Product approved under new proprietary name Besivance.
17.	Opti-one	Boric Acid, Citric Acid Monohydrate, Edetate Disodium, Mannitol, Patinic 138c, Polyquaternium, Purified Water, Sodium Borate, Decahydrate, Sodium Chloride, Sodium Citrate Dihydrate, Sodium Hydroxide, Tetronic 1304	Look alike	Product is a contact lens product.
18.	Optisone	Neomycin Sulfate and Prednisolone	Look alike and sound alike	Name identified in Micromedex database. Unable to find product characteristics in commonly used drug databases.
19.	Aptein	Benzyl Alcohol	Look alike	Name identified in Micromedex database. Unable to find product characteristics in 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.**

No.	<p align="center"><b>Proposed name: Aptiom</b></p> <p align="center"><b>Dosage Form: Tablets</b></p> <p align="center"><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p align="center"><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p align="center"><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p align="center"><b>Causes (could be multiple)</b></p>	<p align="center"><b>Prevention of Failure Mode</b></p> <p align="center"><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	<p>Epzicom (Abacavir Sulfate and Lamivudine) Tablets</p> <p><u>Strength:</u> Abacavir Sulfate 600 mg and Lamivudine 300 mg</p> <p><u>Dosage:</u> One tablet by mouth once daily</p>	<p><u>Orthographic:</u> The first letter ‘e’ and ‘a’ can look similar when scripted. Both names contain a down stroke letter ‘p’ at the second position. Both names end with the letter pair ‘om.’</p> <p><u>Phonetic:</u> Both names contain three syllables with a similar sounding first syllable. The ending of the last syllable ‘om’ in both names is identical.</p> <p><u>Strength:</u> There is numerical overlap between the 600 mg Abacavir Sulfate component of Epzicom and Aptiom 600 mg</p> <p><u>Dosage, dosage form, and route of administration:</u> Both products can be prescribed as “One tablet by mouth.”</p> <p><u>Frequency of administration:</u> Both products are administered once daily.</p>	<p><u>Orthographic:</u> Aptiom contains a cross stroke/upstroke letter at the third position vs. Epzicom does not contain a cross stroke/upstroke letter at the third position. Epzicom contains the extra letter ‘c’ at the fifth position giving the suffix a longer appearance when scripted.</p> <p><u>Phonetic:</u> The beginning of the second syllable ‘zi’ in Epzicom and ‘ti’ in Aptiom sound different when spoken.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
2.	<p>Aptivus (Tipranavir) Capsules and Solution</p> <p><u>Strength:</u> 250 mg Capsules; 100 mg per mL Solution</p> <p><u>Dosage:</u> 500 mg by mouth twice daily; 14 mg/kg by mouth twice daily or 375 mg/m<sup>2</sup> by mouth twice daily in pediatrics</p>	<p><u>Orthographic:</u> Both names begin with 'Apti.'</p> <p><u>Dosage:</u> Since Aptivus can be individualized to patient weight in pediatrics, there is potential overlap between Aptivus 200 mg and Aptiom 200 mg, and Aptivus 400 mg and Aptiom 400 mg.</p> <p><u>Route of administration:</u> Both products are administered orally.</p>	<p><u>Orthographic:</u> The letter string 'vus' in Aptivus and the letter pair 'om' in Aptiom look different when scripted.</p>
3.	<p align="right">(b) (4)</p>		

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
4.	<p>Optivar (Azelastine) Solution</p> <p><u>Strength:</u> 0.05%</p> <p><u>Dosage:</u> Instill one drop in each affected eye twice daily</p>	<p><u>Orthographic:</u></p> <p>The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position.</p>	<p><u>Orthographic:</u></p> <p>The letter string ‘var’ in Optivar and the letter pair ‘om’ in Aptiom look different when scripted.</p> <p><u>Strength:</u></p> <p>Optivar is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. The strengths of Optivar and Aptiom do not overlap.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
5.			

(b) (4)

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
6.	<p>Optase (Castor Oil, Peru Balsam, Trypsin) Gel</p> <p><u>Strength:</u> Castor Oil 788 mg, Peru Balsam 87 mg, and Trypsin 0.12 mg per gram</p> <p><u>Dosage:</u> Apply twice daily as directed or as often as necessary</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter pair ‘pt’ at the second and third position.</p>	<p><u>Orthographic:</u> The letter string ‘ase’ in Optase and the letter string ‘iom’ in Aptiom are different when scripted.</p> <p><u>Strength:</u> Optase is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. The strengths of Optase and Aptiom do not overlap.</p> <p><u>Dosage:</u> Optase can be prescribed as directed or ‘Apply XX amount’ vs. Aptiom can be prescribed as ‘XX tablets’ or ‘XX mg.’</p>

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

No.	<p align="center"><b>Proposed name: Aptiom</b></p> <p align="center"><b>Dosage Form: Tablets</b></p> <p align="center"><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p align="center"><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p align="center"><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p align="center"><b>Causes (could be multiple)</b></p>	<p align="center"><b>Prevention of Failure Mode</b></p> <p align="center"><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
7.	<p>Optimum Acidophilus</p> <p>Optimum Care System</p> <p>Optimum Cleaning/Disinfect/Storage</p> <p>Optimum Evening Primrose Oil</p> <p>Optimum Extra Strength Cleaner</p> <p>Optimum Folic Acid</p> <p>Optimum Vitamin B-1</p> <p>Optimum Vitamin B-Complex</p> <p>Optimum Wetting/Rewetting</p>	<p><u>Orthographic:</u></p> <p>The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position. Both names end with a similar letter pair ‘um’ in Optimum and ‘om’ in Aptiom.</p> <p><u>Phonetic:</u></p> <p>Both names have three syllables with a similar sounding first syllable and an identical sounding second syllable.</p>	<p><u>Orthographic:</u></p> <p>Optimum contains the extra letter ‘m’ in the fifth position, giving the name a longer appearance when scripted. A product with the root name, Optimum, does not exist. A written prescription for Optimum would need to indicate which specific product (i.e. Acidophilus, Care System, etc.) is needed.</p> <p><u>Phonetic:</u></p> <p>A product with the root name, Optimum, does not exist. A verbal prescription for Optimum would need to indicate which specific product (i.e. Acidophilus, Care System, etc.) is needed.</p>

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

No.	<p align="center"><b>Proposed name: Aptiom</b></p> <p align="center"><b>Dosage Form: Tablets</b></p> <p align="center"><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p align="center"><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p align="center"><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p align="center"><b>Causes (could be multiple)</b></p>	<p align="center"><b>Prevention of Failure Mode</b></p> <p align="center"><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
8.	<p>Opticrom (Cromolyn Sodium) Solution</p> <p><u>Strength:</u> 4%</p> <p><u>Dosage:</u> One to two drops in each eye four to six times per day</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position. Both names end with the letter string ‘om.’</p> <p><u>Phonetic:</u> Both names have three syllables with a similar sounding first syllable and an identical sounding second syllable.</p> <p><u>Frequency of administration:</u> There is similarity between the frequencies of administration Opticrom QID and Aptiom QD.</p>	<p><u>Orthographic:</u> Opticrom contains the extra letter pair ‘cr’ in the suffix, giving the name a longer appearance when scripted.</p> <p><u>Phonetic:</u> The onset of the third syllable ‘crom’ in Opticrom contains a ‘cr’ sound that is missing from the onset of the third syllable ‘om’ in Aptiom.</p> <p><u>Strength:</u> Opticrom is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. Although there is numerical similarity between 4% and 400 mg, the numerical similarity is more than 10 fold and the units % and mg may help differentiate the two strengths.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
9.	<p>Optison (Perflutren Protein Type A) Injection</p> <p><u>Strength:</u> Perflutren 0.11 mg to 0.33 mg and Protein Type A <math>5 \times 10^8</math> to <math>8 \times 10^8</math> per mL</p> <p><u>Dosage:</u> 0.5 mL intravenously; may repeat in increments of 0.5 mL up to 5 mL cumulatively in 10 minutes</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position. The letter pair ‘on’ in Optison and the letter pair ‘om’ in Aptiom look similar when scripted.</p> <p><u>Phonetic:</u> Both names have three syllables with a similar sounding first syllable and an identical sounding second syllable.</p>	<p><u>Phonetic:</u> The onset of the third syllable ‘son’ in Optison contains an ‘s’ sound that is missing from the onset of the third syllable ‘om’ in Aptiom.</p> <p><u>Dosage:</u> The dosage of Optison and Aptiom do not overlap and are not achievable within the usual dosage range.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
10.	<div style="text-align: right;">(b) (4)</div>		

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
11.	<p>Optics Eye Wash (Sodium Chloride)</p> <p><u>Strength:</u> 0.9%</p> <p><u>Dosage:</u> Instill one to two drops into affected eye(s) every three to four hours</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position.</p>	<p><u>Orthographic:</u> The letter pair ‘cs’ in Optics and the letter pair ‘om’ in Aptiom look different when scripted.</p> <p><u>Strength:</u> Optics Eye Wash is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. The strengths of Optics Eye Wash and Aptiom do not overlap.</p> <p><u>Frequency of administration:</u> Optics Eye Wash can be administered every three to four hours vs. Aptiom is administered once daily.</p>

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

No.	<p align="center"><b>Proposed name: Aptiom</b></p> <p align="center"><b>Dosage Form: Tablets</b></p> <p align="center"><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p align="center"><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p align="center"><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p align="center"><b>Causes (could be multiple)</b></p>	<p align="center"><b>Prevention of Failure Mode</b></p> <p align="center"><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
12.	<p>Optima 100 (Vitamin B1, Biotin, Pantothenic Acid, Calcium, Magnesium, Zinc, Selenium, Chromium, and Proprietary Blend) Capsules</p> <p><u>Strength:</u> Vitamin B1 8 mg, Biotin 1000 mcg, Pantothenic Acid 8 mg, Calcium 80 mg, Magnesium 60 mg, Zinc 15 mg, Selenium 100 mcg, Chromium 200 mcg, and Proprietary Blend 710 mg</p> <p><u>Dosage:</u> Two capsules by mouth twice daily</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position.</p> <p><u>Dosage and route of administration:</u> Both products can be prescribed as ‘Take two by mouth.’</p>	<p><u>Strength:</u> Optima 100 is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. Although there is numerical overlap between individual ingredients of Optima 100 and Aptiom, it is unlikely for Optima 100, a multiple ingredient product, to be prescribed by the strength of a single ingredient.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
13.	<p>Isoptin (Verapamil) Injection</p> <p><u>Strength:</u> 2.5 mg per mL</p> <p><u>Dosage:</u> 5 mg to 10 mg (0.075 mg/kg to 0.3 mg/kg) intravenously every 15 to 30 minutes up to a total dose of 20 mg; 1 mcg/kg/min to 7 mcg/kg/min intravenously</p>	<p><u>Orthographic:</u> The first letter ‘A’ and ‘I’ look similar when scripted. Both names contain the letter pair ‘pti’ and end with a similar letter ‘n’ vs. ‘m.’</p>	<p><u>Orthographic:</u> The placement of the down stroke letter ‘p’ and the placement of the cross stroke/upstroke letter ‘t’ in Isoptin and Aptiom are different.</p> <p><u>Dosage:</u> Although there is numerical similarity between Isoptin 6 mg and Aptiom 600 mg, and Isoptin 8 mg and Aptiom 800 mg, the difference is 100-fold, minimizing the risk for confusion.</p> <p><u>Frequency of administration:</u> Isoptin is administered as needed every 15 to 30 minutes or by continuous infusion vs. Aptiom is administered once daily.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
14.	FreeStyle Optium Blood Glucose Monitoring System	<p><u>Orthographic:</u></p> <p>The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain the letter string ‘pti’ at the second, third, and fourth position. The letter pair ‘um’ in Optium and the letter pair ‘om’ in Aptiom look similar when scripted.</p> <p><u>Phonetic:</u></p> <p>Both names contain three syllables. The first and third syllable sound similar, and the second syllable ‘ti’ is identical.</p>	<p><u>Orthographic:</u></p> <p>Optium is a model type of the FreeStyle Blood Glucose Monitoring Systems. If “FreeStyle” were written, it would help differentiate the two products.</p> <p><u>Phonetic:</u></p> <p>Optium is a model type of the FreeStyle Blood Glucose Monitoring Systems. If “FreeStyle” were spoken, it would help differentiate the two products.</p> <p><u>Strength:</u></p> <p>Optium does not have a strength since it is a device. Aptiom is available in multiple strengths, and a strength or dose would need to be specified on a prescription.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
15.	<p>Opium Tincture Solution</p> <p><u>Strength:</u> 10 mg per mL</p> <p><u>Dosage:</u> 0.3 mL to 1 mL by mouth four times daily; 0.005 mL/kg to 0.01 mL/kg by mouth every three to four hours.</p>	<p><u>Orthographic:</u> The first letter ‘O’ and ‘A’ look similar when scripted. Both names contain a down stroke letter ‘p’ at the second position. The letter string ‘ium’ in Opium and the letter string ‘iom’ in Aptiom look similar when scripted.</p> <p><u>Phonetic:</u> Both names contain three syllables. The third syllable sounds similar.</p> <p><u>Route of administration:</u> Both products are administered orally.</p> <p><u>Frequency of administration:</u> There is similarity between the frequencies of administration Opium QID and Aptiom QD.</p>	<p><u>Orthographic:</u> Aptiom contains a cross stroke/upstroke letter ‘t’ at the third position vs. Opium does not contain a cross stroke/upstroke letter at the third position.</p> <p><u>Dosage:</u> Although there is numerical similarity between Opium 0.4 mL and Aptiom 400 mg, Opium 0.6 mL and Aptiom 600 mg, and Opium 0.8 mL and Aptiom 800 mg, the difference is 1000-fold, minimizing the risk for confusion.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
16.	<p>Actron (Keotprofen) Tablets</p> <p><u>Strength:</u> 12.5 mg</p> <p><u>Dosage:</u> One to two tablets by mouth every four to six hours</p>	<p><u>Orthographic:</u> Both names begin with ‘A’ and contain a cross stroke/upstroke letter ‘t’ at the third position. The letter string ‘ron’ in Actron and the letter string ‘iom’ in Aptiom look similar when scripted.</p> <p><u>Dosage, dosage form, and route of administration:</u> Both products can be prescribed as ‘Take one tablet by mouth’ or ‘Take two tablets by mouth.’</p> <p><u>Frequency of administration:</u> There is similarity between the frequencies of administration Actron QID (every 6 hours) and Aptiom QD.</p>	<p><u>Orthographic:</u> Aptiom contains a down stroke letter at the second position vs. Actron does not contain a down stroke letter at the second position.</p> <p><u>Strength:</u> Actron is available in a single strength and therefore, the strength may be omitted from a prescription. Aptiom is available in multiple strengths, which would need to be specified on a prescription. The strengths of Actron and Aptiom do not overlap.</p>

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

No.	<p><b>Proposed name: Aptiom</b></p> <p><b>Dosage Form: Tablets</b></p> <p><b>Strength: 200 mg, 400 mg, 600 mg, 800 mg</b></p> <p><b>Dosage: 400 mg once daily increased weekly by 400 mg increments to a maximum of 1,200 mg once daily; renal impairment: 200 mg once daily increased every two weeks by 200 mg increments to a maximum of 600 mg once daily</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
17.	<p>Ceptaz (Ceftazidime) Powder for Injection</p> <p><u>Strength:</u> 1 g, 2 g, 10 g</p> <p><u>Dosage:</u> 250 mg to 2 g intravenously or intramuscularly every 8 to 12 hours; 25 mg/kg to 75 mg/kg intravenously every 8 to 12 hours in pediatrics; 0.5 g intravenously or intramuscularly every 24 to 48 hours</p>	<p><u>Orthographic:</u> The letter pair ‘ce’ and the letter ‘a’ look similar when scripted. Both names contain the letter pair ‘pt.’</p> <p><u>Dosage:</u> Since Ceptaz can be individualized to patient weight in pediatrics, there is potential overlap between Ceptaz 200 mg and Aptiom 200 mg, Ceptaz 400 mg and Aptiom 400 mg, Ceptaz 600 mg and Aptiom 600 mg, and Ceptaz 800 mg and Aptiom 800 mg.</p> <p><u>Frequency of administration:</u> Both products can be administered once daily.</p>	<p><u>Orthographic:</u> The letter pair ‘az’ in Ceptaz and the letter string ‘iom’ in Aptiom look different when scripted.</p> <p><u>Route of administration:</u> Ceptaz can be administered intravenously or intramuscularly, which would need to be indicated on a prescription. The routes of administration for Ceptaz do not overlap with the oral route of administration for Aptiom.</p>

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JULIE V NESHIEWAT  
10/23/2013

IRENE Z CHAN  
10/23/2013

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

**Proprietary Name Review**

Date: August 14, 2013

Reviewer: Julie Neshiewat, PharmD  
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS  
Division of Medication Error Prevention and Analysis

Deputy Director: Kellie Taylor, PharmD, MPH  
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: (b) (4) (Eslicarbazepine Acetate) Tablets  
200 mg, 400 mg, 600 mg, 800 mg

Application Type/Number: NDA 022416

Applicant/Sponsor: Sunovion Pharmaceuticals

OSE RCM #: 2013-1184

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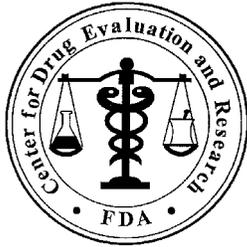
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08/14/2013

IRENE Z CHAN  
08/14/2013

KELLIE A TAYLOR  
08/14/2013



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

Date: July 2, 2009

To: Russell Katz, MD, Director  
Division of Neurology Products

Through: Carlos M Mena-Grillasca, RPh, Acting Team Leader  
Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: L. Shenee' Toombs, PharmD, Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Stedesa (Eslicarbazepine acetate) Tablets  
400 mg, 600 mg, and 800 mg

Application Type/Number: NDA 22-416

Applicant/Applicant: Sepracor

OSE RCM #: 2009-675

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## **EXECUTIVE SUMMARY**

Stedesa is the proposed proprietary name for Eslicarbazepine acetate tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Additionally, our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Stedesa acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, 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.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This review is in response to a request from Sepracor on April 15, 2009, for an assessment of the proposed proprietary name, Stedesa, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study in support of their proposed proprietary name. Sepracor also submitted container labels and carton labeling for review, which will be reviewed under separate cover (OSE Review #2009-996).

### **1.2 PRODUCT INFORMATION**

Stedesa (Eslicarbazepine acetate) is an antiepileptic drug being investigated for adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. The usual maintenance dose is 800 mg once daily, and the maximum recommended daily dose is 1,200 mg once daily. Stedesa will be supplied as 400 mg, 600 mg, and 800 mg tablets in bottles of 30, 60, and 90 tablets.

### **1.3 REGULATORY HISTORY**

Stedesa (Eslicarbazepine acetate) is currently under review by the Division of Neurology Products under NDA 22-416 with a PDUFA goal date of January 30, 2010.

## **2 METHODS AND MATERIALS**

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Stedesa.

### **2.1 SEARCH CRITERIA**

For this review, particular consideration was given to drug names beginning with the letter 'S' 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.<sup>1,2</sup>

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<sup>1</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

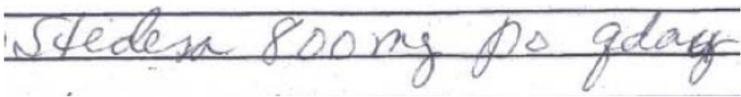
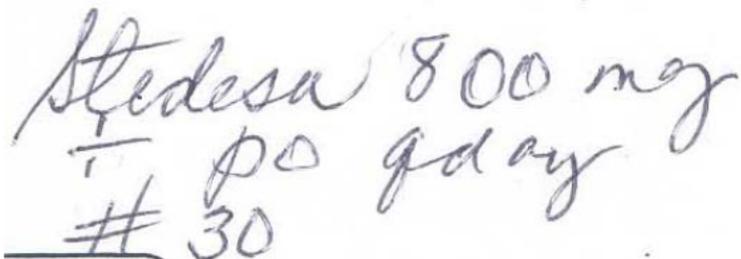
To identify drug names that may look similar to Stedesa, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (three, capital letter 'S', lowercase letter 't' and lowercase letter 'd'), down strokes (none), cross strokes (one, lowercase letter 't'), and dotted letters (none). Additionally, several letters in Stedesa may be vulnerable to ambiguity when scripted, including the capital letter 'S' may appear as capital letters 'G', 'D', 'A', 'C', 'L' or 'T'; lower case 't' may look like lower case 'l', 'r', 'k', 'x' or 'f'; lower case 'e' may look like lower case 'a', 'i', 'o' or 'c'; lower case letter 'd' may appear as lower case 'cl'; lower case 's' may appear as lower case 'a', 'c', 'n' or 'r'; lower case 'a' may appear as lower case 'e', 'i', 'o', or 'c'. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Stedesa.

When searching to identify potential names that may sound similar to Stedesa, the DMEPA staff search for names with similar number of syllables (3), stresses (STE-de-sa; ste-DE-sa; ste-de-SA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as '-de-' may sound like 'da', and 'du', and '-sa' may sound like 'za', 'zu', 'zuh', 'zeh', 'she', and 'suh'. The Applicant's intended pronunciation (ste-de'-sah) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient medication order and verbal prescription was communicated during the FDA prescription studies.

**Figure 1. Stedesa Study (conducted on May 13, 2009)**

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	<p>Stedesa 800 mg Dispense: #30 Take 1 tab po daily</p>
<p><u>Outpatient Medication Order:</u></p> 	

## 2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis 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 DMEPA'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 associated with 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 Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

## 3 RESULTS

### 3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of nine names as having some similarity to the name Stedesa.

All nine names were thought to look like Stedesa. These include: Genesa, (b) (4) Stalevo, (b) (4) Stediril, Stelara\*\*\*, (b) (4) Strattera, and Verdeso.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 27, 2009.

### 3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Stedesa.

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

### 3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of nineteen practitioners responded in the prescription analysis studies. Ten of the participants interpreted the name correctly as "Stedesa," with correct interpretation occurring in both the inpatient and outpatient written studies. The remainder of the written responses misinterpreted the drug name. In the verbal studies, all responses were misspelled phonetic variations of the proposed name, Stedesa. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

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### **3.4 EXTERNAL STUDY**

In the proposed name risk assessment submitted by the Applicant, (b) (4) identified and evaluated a total of twenty-eight names thought to have some potential for confusion with the name Stedesa: Amphadase, Cedax, Cetaderm, Cidex, Cyclessa, Histade, Histadec, Histadec DM, Iressa, Precedex, Seba-gel, Sebex, Simcor, Sta-D, Stadol, Stadol NS, Stagesic, Stahist, Stalevo, Stelazine, Sterapred, Streptase, Stri-dex, Trinessa, Vistide, Xedec, Zavesca and Zebeta. DMEPA identified Stalevo and Zavesca during their evaluation. The remaining twenty-six names were evaluated in Section 3.6 below.

### **3.5 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)**

In response to the OSE, April 28, 2009 e-mail, DNP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

On June 10, 2009, DMEPA notified the Division of Neurology Products via e-mail that we had no objections to the proposed proprietary name, Stedesa. Per e-mail correspondence from the Division of Neurology Products on June 17, 2009, they indicated that they concur with our assessment of the proposed proprietary name, Stedesa.

### **3.6 SAFETY EVALUATOR RISK ASSESSMENT**

Independent searches by the primary Safety Evaluator identified five additional names which were thought to look or sound similar to Stedesa and represent a potential source of drug name confusion.

Two of the five names, Stadasan and Stedon look similar to Stedesa. One name, Zavesca, was identified to have sound-alike similarities. Two names, Sedesa and Stadesa, were identified as having sound-alike and look-alike similarities to Stedesa. Upon further observation, the latter name Stadesa, was found to be a misspelling of the proposed proprietary name due to shared product characteristics (i.e. established name, sponsor name, therapeutic classification). Therefore, Stadesa was eliminated from further analysis. Thus, we evaluated a total of 39 names for their similarity to the proposed name.

## **4 DISCUSSION**

Neither DDMAC nor the Division of Neurology Products had concerns with the proposed name. DMEPA identified and evaluated thirty-nine names for their potential similarity to the proposed name, Stedesa. Twenty-three of the thirty-nine names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining sixteen names and lead to medication errors. This analysis determined that the name similarity between Stedesa was unlikely to result in medication errors with any of the sixteen products for the reasons presented in Appendices D through G. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

## **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Stedesa, is not vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Stedesa, for this product at this time. Our assessment supports the findings of the External Study submitted by the Applicant.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Dan Brounstein, project manager, at 301-796-0674.

## **5.1 COMMENTS TO THE APPLICANT**

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

Stedesa will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

## 6 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. ***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>)

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](http://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](http://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](http://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. Stat!Ref ([www.statref.com](http://www.statref.com))**

Stat!Ref contains full-text information from approximately 30 texts; it 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>)**

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](http://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 potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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.<sup>3</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

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. DMEPA bases

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<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

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. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.<sup>5</sup> DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares 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. DMEPA staff also examines 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 even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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<sup>4</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

<sup>5</sup> 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"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
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"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

Lastly, the DMEPA staff also 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 staff conducts searches 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 the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA 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 some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review 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.

## **2. CDER Expert Panel Discussion**

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. 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). 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 DMEPA staff 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 primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

## **3. FDA 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 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 the 123 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 DMEPA.

## **4. Comments from the OND review Division or Generic drugs**

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 or 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 concur/not concur with DMEPA's final decision.

## 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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.<sup>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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. 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.

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 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

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<sup>6</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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.

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 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. In that instance, DMEPA may be able to provide the Applicant 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. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug 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 a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, 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 approving the error-prone proprietary name. Moreover, even after Applicants' 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. . (See Section 4 for limitations of the process).

**Appendix B: FDA Prescription Study Responses.**

<b>Inpatient Medication Order</b>	<b>Outpatient Medication Order</b>	<b>Voice Prescription</b>
Stedesa	Stedesa	Stadessa
Stedesa	Stedesa	Fedessa
Stedesa	Stedesa	Fidessa
Stedesa	Stedesa	Dedessa
Siledesa		Fadessa
Stedesa		Fidessa
Stedesa		Stadessa
		Fedessa

**Appendix C: Proprietary names that lack convincing orthographic and/or phonetic similarities**

<b>Proprietary Name</b>	<b>Similarity to Stedesa</b>
Amphadase	(b) (4)
Cedax	
Cetaderm	
Cidex	
Cyclessa	
Genesa	Look
Histade	(b) (4)
Histadec	
Histadec DM	
Precedex	
Seba-gel	
Sebex	
Simcor	
Sta-D	
Stadol NS	
Stagesic	
Stahist	
Stelazine	
(b) (4)	Look
Sterapred	(b) (4)
Streptase	
Vistide	
Xedec	

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

**Appendix D:** Proprietary names that are internationally registered

Proprietary Name	Similarity to Stedesa	Country
Stadasan	Look	Germany
Stedon	Look	Greece
Sedes A	Look and Sound	Taiwan
Stederil	Look	Belgium, France

**Appendix E:** Product marketed under a different proprietary name

Proprietary Name	Similarity to Stedesa	Reason for Discard
(b) (4)	Look	Approved under the name Edluar

**Appendix F:** Products with no numerical overlap in strength and usual dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Stedesa (Eslicarbazepine ) Tablet		400 mg, 600 mg, 800 mg	Initial: 400 mg once a day Maintenance: 800 mg once a day Maximum recommended daily dose: 1200mg
Verdeso (Desonide)	Look	Topical (aerosol): 0.05%	Apply to affected area twice daily
Trinessa	(b) (4)	Tablet: (Triphasic) 0.18 mg norgestimate/ 35 mcg ethinyl estradiol 0.215 mg norgestimate/ 35 mcg ethinyl estradiol 0.25 mg norgestimate/ 35mcg ethinyl estradiol	One tablet once daily

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**Appendix F (cont'd): Products with no numerical overlap in strength**

Stelara*** (Ustekinumab)	Look	Injection: 45 mg, 90 mg	Initial: Administer 45 mg or 90 mg subcutaneously; Repeat in 4 weeks.  Maintenance: Administer 45 mg or 90 mg subcutaneously every 12 weeks.
Stridex (Salicylic acid)	(b) (4)	Topical: Pads: 0.5 %, 1.0%, 2.0%	Cleanse face with one pad 1 to 3 times daily
Iressa	(b) (4)	Tablet: 250 mg	250 mg once daily  500 mg once daily (with concomitant CYP3A4 inducers)
Stadol (Butorphanol)	(b) (4)	Injection: 2 mg/mL	Intravenous: 0.5 mg to 1 mg every 3 to 4 hours Intramuscular: 1 mg to 2 mg every 3 to 4 hours
Zebeta (Bisoprolol)	(b) (4)	Tablets: 5 mg, 10 mg	Treatment of hypertension, heart failure and angina  5 mg to 20 mg once daily

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

**Appendix G:** Proprietary names with achievable dose but not vulnerable to confusion with Stedesa due to differing product characteristics.

<b>Proposed name:</b> Stedesa (Eslicarbazepine ) Tablet	<b>Strength:</b> 400 mg, 600 mg, 800 mg	<b>Usual dose:</b> Initial: 400 mg once a day Maintenance: 800 mg once a day Maximum recommended daily dose: 1200mg
<b>Failure Mode:</b> Name confusion	<b>Causes (could be multiple)</b>	<b>Rationale:</b>
Zavesca (Miglustat) Capsule: 100 mg  <i>Indication:</i> Type 1 Gaucher disease  Dose: 100 mg three times a day	<p><b>Phonetic similarity:</b>                      Both names have three syllables                      Both names have similar sounding first syllables ‘Ste’ vs ‘Za’                      Both names have rhyming second (‘de’ vs. ‘ve’) and third (‘sa’ vs. ‘sca’) syllables.</p> <p><b>Achievable/Overlapping dose:</b>  <i>scenario 1</i>                      Orders/prescriptions written as Stedesa, being interpreted as Zavesca                      for example:                      Stedesa 400 mg po qday → Zavesca 400 mg po qday  <i>scenario 2</i>                      Orders/prescription written as Zavesca, being interpreted as Stedesa.                      for example:                      Zavesca 100 mg po three times a day → Stedesa 100 mg po three times a day.</p>	<p>Medication errors unlikely to occur due to differing frequencies of administration and the maximum daily amount of Zavesca is below the recommended dose of Stedesa.</p> <p><i>Rationale:</i></p> <p>For scenario 1, the frequency of administration of the two products is different, and would alert the dispenser to question the once daily dosing of Zavesca. Furthermore, a 400 mg dose of Zavesca, is above the 300 mg maximum daily amount recommended for this drug.</p> <p>This rationale is also valid for the 600 mg and 800 mg strengths of Stedesa.</p> <p>For scenario 2, if an order/prescription is written or misinterpreted as Stedesa. The dispenser would have to question the order considering Stedesa is not supplied in a 100 mg strength. Furthermore, Stedesa is dosed once a day, and a three-times-a-day frequency would also alert the dispenser.</p>

**Appendix G (cont'd):** Proprietary names with achievable dose but not vulnerable to confusion with Stedesa due to differing product characteristics.

<b>Proposed name:</b> Stedesa (Eslicarbazepine ) Tablet	<b>Strength:</b> 400 mg, 600 mg, 800 mg	<b>Usual dose:</b> Initial: 400 mg once a day Maintenance: 800 mg once a day Maximum recommended daily dose: 1200mg
<b>Failure Mode:</b> Name confusion	<b>Causes (could be multiple)</b>	<b>Rationale:</b>
(b) (4)		

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

**Appendix G (cont'd):** Proprietary names with achievable dose but not vulnerable to confusion with Stedesa due to differing product characteristics.

<b>Proposed name:</b> <b>Stedesa</b> <b>(Eslicarbazepine )</b> <b>Tablet</b>	<b>Strength:</b> <b>400 mg, 600 mg, 800 mg</b>	<b>Usual dose:</b> <b>Initial: 400 mg once a day</b> <b>Maintenance: 800 mg once a day</b> <b>Maximum recommended daily dose: 1200mg</b>
<b>Failure Mode:</b> <b>Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Rationale:</b>
<p>Strattera (Atomoxetine) Capsules: 5 mg, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg</p> <p><i>Indication:</i> Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)</p> <p>Dose: Children (up to 70 kg): 0.5 mg/kg to 1.4 mg/kg in a single or divided doses</p> <p>Adults and Children (over 70 kg): 40 mg to 80 mg in a single or divided doses</p>	<p><b>Orthographic similarity:</b></p> <p>Both names begin with the letters ‘St’</p> <p>Both names end with the letter ‘a’</p> <p><b>Achievable/Overlapping dose:</b></p> <p><i>scenario 1</i> Orders/prescriptions written as Stedesa, being interpreted as Strattera.</p> <p>for example: Stedesa 400 mg po qday → Strattera 400 mg po qday</p> <p><i>scenario 2</i> Orders/prescription written as Strattera, being interpreted as Stedesa.</p> <p>for example: Strattera 100 mg po qday → Stedesa 100 mg po qday. Strattera 40 mg po bid → Stedesa 40 mg bid</p>	<p>Medication errors unlikely to occur due to the maximum daily amount of Strattera being lower than the recommended dosing of Stedesa and the differing frequency of administration.</p> <p><i>Rationale:</i></p> <p>For scenario 1, a 400 mg dose of Strattera, is above the 100 mg maximum daily amount allowed for this drug, and would alert the dispenser to question the order. This rationale is also valid for the 600 mg and 800 mg strengths of Stedesa.</p> <p>For scenario 2 (example 1). If an order/prescription is written or misinterpreted as Stedesa, the dispenser would have to question the order considering Stedesa is not supplied in a 100 mg strength. This rationale is valid for the remaining strengths of Strattera</p> <p>For scenario 2 (example 2). The dispenser would have to question the order considering Stedesa is not supplied in a 40 mg strength. Furthermore, Stedesa is dosed once a day, and a twice daily frequency would also alert the dispenser to question the order. This rationale is also valid for the remaining strengths of Strattera.</p>

**Appendix G (cont'd):** Proprietary names with achievable dose but not vulnerable to confusion with Stedesa due to differing product characteristics.

<b>Proposed name:</b> <b>Stedesa</b> <b>(Eslicarbazepine )</b> <b>Tablet</b>	<b>Strength:</b> <b>400 mg, 600 mg, 800 mg</b>	<b>Usual dose:</b> <b>Initial: 400 mg once a day</b> <b>Maintenance: 800 mg once a day</b> <b>Maximum recommended daily dose: 1200mg</b>
<b>Failure Mode:</b> <b>Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Rationale:</b>
<p>Stalevo (Carbidopa and Entacapone and Levodopa)</p> <p>Tablets: 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 200 mg</p> <p><i>Indication:</i> Parkinson's disease</p> <p>Dose: Variable dosing</p>	<p><b>Orthographic similarity:</b> Both names are similar in shape (upstrokes) and length (7 letters)</p> <p><b>Phonetic similarity:</b> Both names have three syllables Both names have similar sounding first syllables 'Ste' vs 'Sta'</p> <p><b>Achievable/Overlapping dose:</b></p> <p><i>scenario 1</i> Orders/prescriptions written as Stedesa, being interpreted as Stalevo for example: Stedesa 400 mg po qday → Stalevo 400 mg po qday</p> <p><i>scenario 2</i> Orders/prescription written as stalevo, being interpreted as Stedesa. for example: Stalevo 200 mg po three times a day → Stedesa 200 mg po three times a day.</p>	<p>Medication errors unlikely to occur due to differing frequencies of administration due to the titration of levodopa in the treatment of idiopathic Parkinson's disease.</p> <p><i>Rationale:</i> Due to the nature of Parkinson's disease, treatment is required throughout the day. Stalevo is an immediate release product and it is therefore unlikely to see a patient with once daily dosing of Stalevo.</p> <p>The titration of levodopa is accomplished in a dose/frequency escalating fashion. When more levodopa is required, the next higher strength should be taken and/or the frequency of doses should be increased to the maximum daily amounts (see below)</p> <p>Maximum daily amounts: Stalevo 50 mg, 75 mg, 100 mg, 125 mg, 150 mg: One tablet 8 times daily Stalevo 200 mg: One tablet 6 times daily</p> <p>For scenario 1, a dispenser should question a once daily frequency and a 400 mg dose of Stalevo, due to the above stated rationale. This rationale is also valid for the remaining strengths of Stedesa.</p> <p>For scenario 2, a dispenser should question the three times a day frequency of Stedesa, since it should be dosed once daily. Furthermore, Stedesa is not supplied in a 200 mg strength. This rationale is valid for the remaining strengths of Stalevo.</p>

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