

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**202129Orig1s000**

**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: January 12, 2011

Reviewer(s): Lissa C. Owens, PharmD  
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Drug Name(s) and Strength(s): Zetonna (Ciclesonide) Nasal Aerosol  
37 mcg per actuation

Application Type/Number: NDA 202129

Applicant/Sponsor: Sunovion Pharmaceuticals Inc.

OSE RCM #: 2011-4672

\*\*\* 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, Zetonna, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

### 1.1 BACKGROUND AND REGULATORY HISTORY

Ciclesonide is currently marketed under the proprietary names Omnaris (NDA 022004) approved in October 2006 and Alvesco (NDA 021658) approved January 2008.

Omnaris is indicated for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and children six years of age and older and perennial allergic rhinitis in adults and adolescents 12 years of age and older. It is supplied in a 12.5 gram bottle that delivers 120 actuations of 50 mcg per actuation. The usual dosage is two sprays per nostril once daily.

Alvesco is indicated for the maintenance treatment of asthma as prophylactic therapy in adults and adolescent patients 12 years of age and older. It is supplied in a 6.1 gram canister that delivers 60 actuations of either 80 mcg or 160 mcg per actuation. The usual dosage is one to two inhalations by mouth twice daily.

The Applicant initially submitted the proposed name (b) (4) which was found unacceptable by DMEPA and communicated to the applicant via teleconference call. DMEPA had concerns (b) (4)

(b) (4) The Applicant subsequently withdrew the name and submitted the proposed proprietary name (b) (4) which was found unacceptable in OSE review # 2011-2623, dated October 21, 2011 (b) (4). The Applicant subsequently submitted the proposed proprietary name, (b) (4) which was found unacceptable by DMEPA (b) (4). This was communicated to the applicant via teleconference call. The Applicant subsequently withdrew the name and submitted the current proposed proprietary name, Zetonna.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the December 27, 2011 proprietary name submission.

- Established Name: Ciclesonide
- Indication of Use: Treatment of Symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older
- Route of administration: Nasal
- Dosage form: Nasal Aerosol
- Strengths: 37 mcg per actuation
- Dose: 74 mcg per day given as one actuation per nostril once daily

- How Supplied: 6.1 g; 30 day supply (60 actuations) and 4.7 g; 15 day supply (30 actuations)
- Storage: 25°C (77°F) excursions between 59-86°F are permitted
- Container and Closure systems: a canister inserted into a purple/white nasal actuator with a purple dust cap
- Intended pronunciation: Ze toe' nah or zet on' ah

## **2 RESULTS**

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

### **2.1 PROMOTIONAL ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products concurred with the findings of OPDP's promotional assessment of the proposed name.

### **2.2 SAFETY ASSESSMENT**

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

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

The United States Adopted Name (USAN) stem search conducted on December 28, 2011, identified that a USAN stem is not present in the proposed proprietary name.

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

The Applicant states that there is no derivation or intended meaning of the proposed proprietary name.

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

#### ***2.2.3 Medication Error Data Selection of Cases***

DMEPA searched AERS database (or other databases) for medication errors involving Ciclesonide which would be relevant for this review.

The October 24, 2011 search of the Adverse Event Reporting System (AERS) database used the following search terms: trade name "Ciclesonide", and verbatim term "Ciclesoni%".

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, there were no reports included in the final analysis for the following reasons: cases did not describe a medication error, adverse events not related to medication errors (e.g. intentional overdose, product quality issues), patient non-adherence, and medication errors not involving this product.

### 2.2.4 FDA Name Simulation Studies

Twenty-five practitioners responded to DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Sixteen out of 25 participants interpreted the name correctly as Zetonna. Three participants interpreted the name correctly as Zetonna, but included portions of the instructions for use in their responses (i.e. Zetonna One, Zetonna One Spray, and Zetonna Bue Spray). Common misinterpretations included the use of a single ‘n’ instead of ‘nn’ (n=5; voice study) and ‘i’ instead of ‘e’ (n=3; voice study). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

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

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Zetonna. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Zetonna identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or (b) (4) not identified by DMEPA and that require further evaluation.

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and FDA Name Simulation Studies (b) (4))**

Look Similar					
Name	Source	Name	Source	Name	Source
Zolinza	Both	Zolyse	FDA	Makena	FDA
Zelapar	FDA	Zatean-Pn	FDA	Zetran	FDA
Zelboraf	FDA	Latairis	FDA	(b) (4)	FDA
Zaleplon	FDA	Latisse	FDA	(b) (4)	FDA
Zoladex	FDA	Mentax	FDA	Retavase	FDA
Zoloft	FDA	Letairis	FDA	Cetacaine	FDA
Zolpidem	FDA	Zolene	FDA	Catarase	FDA
Zolpimist	FDA	Lutera	FDA	(b) (4)	(b) (4)
Sound Similar					
Zofran	(b) (4)	Jevtana	(b) (4)	Belladonna	(b) (4)
Sonata	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

<b>Look and Sound Similar</b>					
Zometa	(b) (4)	Zebeta	(b) (4)	Sufenta	(b) (4)
Zotane HC	Both	Zelnorm	Both	Acetone	
Zetia	Both	Xeloda	Both	Zetonna***	FDA
Ziana	Both				

Our analysis of the thirty-seven names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that all 37 names will not pose a risk for confusion as described in Appendices D through E.

### ***2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines***

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology via e-mail on January 10, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products, they stated no additional concerns with the proposed proprietary name, Zetonna.

## **3 CONCLUSIONS**

The proposed proprietary name, Zetonna is acceptable from both a promotional and safety perspective. If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904

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

We have completed our review of the proposed proprietary name, Zetonna, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your December 27, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

## 4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

### 8. *Clinical Pharmacology Online* ([www.clinicalpharmacology-ip.com](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. **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.

10. **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.

11. **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.

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

USAN Stems List contains all the recognized USAN stems.

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

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

14. **Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

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

15. **Medical Abbreviations Book**

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

16. **CVS/Pharmacy ([www.CVS.com](http://www.CVS.com))**

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

17. **Walgreens ([www.walgreens.com](http://www.walgreens.com))**

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

18. **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.

19. **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.

## 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>1</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.

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,

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

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>2</sup> The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

<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-	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>

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

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

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

### **3. FDA Prescription Simulation Studies**

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

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

### **4. Comments from Other Review Disciplines**

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

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

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

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

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>3</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 Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug 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

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

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.

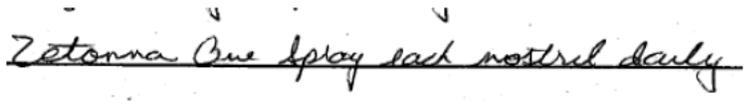
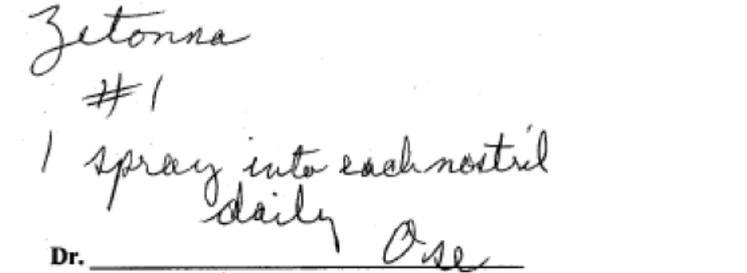
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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, Zetonna	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'Z'	'2', 'C', 'f', 'l', 'M', 'T', 'S', 'V', 'Y'	'C', 'S', 'X'
lower case 'e'	'a', 'i', 'l', 'o', 'u', 'p'	Any vowel
lower case 'n'	'm', 'u', 'x', 'r', 'h', 's'	m
lower case 't'	'r', 'f', 'x', 'A'	'd'
lower case 'a'	'e', 'el', 'ci', 'cl', 'd', 'o', 'u'	Any Vowel
lower case 'o'	'a', 'c', 'e', 'u'	'Oh', any vowel

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

**Figure 1. Zetonna Study (Conducted on January 4, 2012)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p>  <p><u>Outpatient Prescription:</u></p> 	<p>Zetonna #1 Spray into each nostril once daily</p>

## FDA Prescription Simulation Responses

85 People Received Study

25 People Responded

Study Name: Zetonna

Total	11	7	7		
	INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
ZATANA	0	2	0	0	2
ZETONNA	8	1	7	0	16
ZETONNA BUE SPRAY	1	0	0	0	1
ZETONNA ONE	1	0	0	0	1
ZETONNA ONE SPRAY	1	0	0	0	1
ZITANA	0	1	0	0	1
ZITONA	0	1	0	0	1
ZITONNA	0	1	0	0	1
ZYTANA	0	1	0	0	1

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

Proprietary Name	Active Ingredient	Similarity to Zetonna	Failure preventions
Zelboraf	Vemufafenib	Look	Lacks convincing orthographic similarity to proposed name
Zaleplon	Zaleplon	Look	Lacks convincing orthographic similarity to proposed name
Zoloft	Sertraline	Look	Lacks convincing orthographic similarity to proposed name
Zolpidem	Zolpidem	Look	Lacks convincing orthographic similarity to proposed name
Zolpimist	Zolpidem tartrate	Look	Lacks convincing orthographic similarity to proposed name
Zolyse	Chymotrypsin	Look	Lacks convincing orthographic similarity to proposed name

Proprietary Name	Active Ingredient	Similarity to Zetonna	Failure preventions
Latairis	N/A	Look	Misspelling of Letairis by a safety evaluator.
Mentax	Butenafine hydrochloride	Look	Lacks convincing orthographic similarity to proposed name
(b) (4)			
Zofran	Ondansetron HCL	Sound	Lacks convincing phonetic similarity to proposed name
Catarase	Chymotrypsin	Look	NDA 016938 withdrawn FR effective June 10, 1999 and NDA 018121 withdrawn FR effective May 29, 2002
Belladonna	Belladonna Alkaloids	Sound	Lacks convincing phonetic similarity to proposed name
Ziana	Clindamycin phosphate, tretinoin	Look and Sound	Lacks convincing orthographic and phonetic similarity to proposed name
Zebeta	Bisoprolol fumarate	Look and Sound	Lacks convincing orthographic and phonetic similarity to proposed name
Sufenta	Sufentanil citrate	Look and Sound	Lacks convincing orthographic and phonetic similarity to proposed name
Acetone	Acetone	Look and Sound	Acetone is not a drug, but a solvent used in: cleaning applications, as a denaturant, precursor of methyl methacrylate, synthesis of bisphenol A, food additive, chemical peelings, etc. Unlikely to be written in a prescription.
Zetonna***	Ciclesonide	Look and Sound	Proposed name for this product found on USPTO
Zetran	Clorazepate	Look	International name (Canada) not marketed in the United States.
(b) (4)			

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

<p><b>Proposed name:</b> <b>Zetonna</b></p>	<p><b>Strength(s):</b> <b>37 mcg per actuation</b></p>	<p><b>Usual dose:</b> <b>One spray into each nostril 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>Zolinza (Vorinostat) Capsules, 100 mg <u>Usual Dose:</u> Four capsules once a day</p>	<p><u>Orthographic:</u> Both names share the letters ‘Z’, ‘n’, and ‘a’ in the same positions and have an upstroke (‘t’ vs. ‘l’) in the third position.  <u>Strength:</u> Both single strength products and therefore strength may be omitted  <u>Frequency of administration:</u> Both are once daily</p>	<p><u>Orthographic:</u> Zetonna appears longer when scripted due to the presence of the ‘nm’ in the 5<sup>th</sup> and 6<sup>th</sup> positions. The upstroke in letter ‘t’ in Zetonna provides a cross stroke that is not seen in Zolinza. The second ‘z’ in Zolinza may be scripted with a down stroke, which would further differentiate the names.  Dosage form, route of administration and dose: Zetonna is an nasal inhaler dosed one inhalation in each nostril vs. Zolinza is dosed as 4 capsules orally. There is no dose overlap.</p>
<p>Zelapar (Selegiline Hydrochloride) Orally disintegrating Tablets, 1.25 mg <u>Usual Dose:</u> 1.25 mg to 2.5 mg once a day</p>	<p><u>Orthographic:</u> Both names share the letters ‘Ze’ in the same positions and have an upstroke (‘t’ vs. ‘l’) in the third position.  <u>Strength:</u> Both single strength products and therefore strength may be omitted  <u>Frequency of administration:</u> Both are once daily</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted ‘nna’ and ‘par’. The upstroke in letter ‘t’ in Zetonna provides a cross stroke that is not seen in Zelapar. Zetonna appears longer when scripted due to the presence of the ‘nm’ in the 5<sup>th</sup> and 6<sup>th</sup> position.  Dosage form, route of administration and dose: Zetonna is an nasal inhaler dosed one spray in each nostril vs. Zelapar is dosed as 1 to 2 tablets on the tongue. There is no dose overlap.</p>

<b>Proposed name:</b> <b>Zetonna</b>	<b>Strength(s):</b> <b>37 mcg per actuation</b>	<b>Usual dose:</b> <b>One spray into each nostril daily</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Zoladex (Goserelin acetate) Implant, 10.8 mg</p> <p><u>Usual Dose:</u> 10.8 mg subcutaneously every 12 weeks</p>	<p><u>Orthographic:</u> Both names begin with the letter 'Z' and have an upstroke ('t' vs. 'l') in the third position. Both have similar looking letters in the same positions ('e' vs. 'o', and 'o' vs. 'a').</p> <p><u>Strength:</u> Both single strength products and therefore strength may be omitted</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted 'nna' and 'dex'. The upstroke in letter 't' in Zetonna provides a cross stroke that is not seen in Zoladex. Additionally, Zoladex has two upstrokes vs. one in Zetonna, giving the names different shapes when scripted.</p> <p><u>Dosage form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Zoladex which is an implant administered as 10.8 mg or 1 implant subcutaneously every 12 weeks.</p>
<p>Latisse (Bimatoprost) Solution, 0.3 mg/mL</p> <p><u>Usual Dose:</u> Apply nightly directly to the skin of the upper eyelid margin at the base of the eyelashes using the accompanying applicators</p>	<p><u>Orthographic:</u> When scripted 'Z' and 'L' may look similar therefore they have similar beginning letter strings, 'Zet' and 'Lat'. Both names includes double letters 'nn' vs. 'ss'.</p> <p><u>Strength:</u> Both single strength products and therefore strength may be omitted</p>	<p><u>Orthographic:</u> The letter string 'onn' looks different than the letter string 'iss'. Zetonna appears longer when scripted due to the presence of the 'nn' in the 5<sup>th</sup> and 6<sup>th</sup> position</p> <p><u>Usual Dose:</u> Zetonna is administered as one spray into each nostril daily versus Latisse which is applied nightly directly to the skin of the upper eyelid margin at the base of the eyelashes using the accompanying applicators.</p> <p><u>Dosage Form/Route of administration:</u> Zetonna is a nasal aerosol vs. Latisse is a topical solution supplied with an applicator.</p>
<p>Letairis (Ambrisentan) Tablets, 5 mg and 10 mg</p> <p><u>Usual Dose:</u> 5 mg to 10 mg by mouth once daily</p>	<p><u>Orthographic:</u> When scripted 'Z' and 'L' may look similar therefore they have similar beginning letter strings, 'Zet' and 'Let'</p> <p><u>Usual Dose:</u> Both are once daily</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted 'nna' and 'ris'. Zetonna appears longer when scripted due to the presence of the 'nn' in the 5<sup>th</sup> and 6<sup>th</sup> position</p> <p><u>Strength:</u> Single strength which may be omitted from the prescription versus Multiple strengths which would have to be listed on the prescription. No strength or dose overlap.</p>

<b>Proposed name:</b> <b>Zetonna</b>	<b>Strength(s):</b> <b>37 mcg per actuation</b>	<b>Usual dose:</b> <b>One spray into each nostril daily</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
Zatean-Pn (Prenatal multi-vitamin and multi-mineral with Iron) Tablets  <u>Usual Dose:</u> One tablet by mouth once a day	<u>Orthographic:</u> Both have similar beginning letter strings ‘Zet’ and ‘Zat’  <u>Strength:</u> Both single strength products and therefore strength may be omitted  <u>Usual Dose:</u> Both are once daily	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘tean’ of the root name. Zetonna has no modifiers versus Zatean which has the modifier ‘Pn’. Additionally, if scripted, the ‘P’ can provide an upstroke or a downstroke (‘p’) not seen on Zetonna.  Preliminary drug use data shows no prescribing for Zatean-Pn.
Zolene HC (Pramoxine, Hydrocortisone, Chloroxylenol) Otic Solution, 10 mg/10 mg/1 mg  <u>Usual Dose:</u> 3 to 5 drops into the affected ear(s) 3 to 4 times per day	<u>Orthographic:</u> Both have similar beginning letter strings ‘Zet’ and ‘Zol’  <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘lene’ of the root name. Zetonna has no modifiers versus Zolene which has the modifier ‘HC’  <u>Usual Dose:</u> Zetonna is administered as one spray into each nostril daily versus Zolene HC which is administered as 3 to 5 drops into the affected ear(s) 3 to 4 times per day  <u>Dosage Form/Route of administration:</u> Zetonna is a nasal inhaler vs. Zolene HC is a topical (otic) solution.  Preliminary drug use data shows no prescribing for Zolene HC.
Lutera (Levonorgestrel and Ethinyl Estradiol) Tablets, 0.1 mg/0.02 mg  <u>Usual Dose:</u> One tablet by mouth once daily	<u>Orthographic:</u> When scripted ‘Z’ and ‘L’ may look similar making the beginning letter strings, ‘Zet’ and ‘Lut’ similar  <u>Strength:</u> Both single strength products and therefore strength may be omitted  <u>Usual Dose:</u> Both are once daily	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘tera’. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5 <sup>th</sup> and 6 <sup>th</sup> position and has 7 letters vs. 6 letters in Lutera.  <u>Dosage Form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Lutera which is an oral tablet taken once daily. There is no dose overlap.

<b>Proposed name:</b> <b>Zetonna</b>	<b>Strength(s):</b> <b>37 mcg per actuation</b>	<b>Usual dose:</b> <b>One spray into each nostril daily</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
Zometa (Zoledronic acid) Injection, 4 mg/vial <u>Usual Dose:</u> 4 mg intravenously every 3 to 4 weeks	<u>Orthographic:</u> Both have similar beginning letter strings ‘Ze’ and ‘Zo’ and an upstroke letter ‘t’. <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘meta’. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5 <sup>th</sup> and 6 <sup>th</sup> position <u>Dosage Form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Zometa which is an injection administered as 4 mg intravenously every 3 to 4 weeks. There is no dose overlap.
Zotane HC (Pramoxine, Hydrocortisone, Chloroxylenol) Otic Solution, 10 mg/10 mg/1 mg <u>Usual Dose:</u> 3 to 5 drops into the affected ear(s) 3 to 4 times per day	<u>Orthographic:</u> Both have similar beginning letter strings ‘Zet’ and ‘Zot’ <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘ane’ of the root name. Zetonna has no modifiers versus Zotane which has the modifier ‘HC’. <u>Dosage Form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Zotane HC which is an otic solution administered as 3 to 5 drops into the affected ear(s) 3 to 4 times per day. There is no dose overlap. Preliminary drug use data shows no prescribing for Zotane HC.
Jevtana (Cabazitaxel) Injection, 60 mg/1.5 mL <u>Usual Dose:</u> 25 mg/m <sup>2</sup> /dose by intravenous infusion every three weeks	<u>Phonetic:</u> Both have 3 syllables with the same 2 <sup>nd</sup> and 3 <sup>rd</sup> syllables <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Phonetic:</u> The 1 <sup>st</sup> syllables ‘Zet’ and ‘Jev’ distinguish the two names when spoken <u>Dosage form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Jevtana which is an injection administered as 25 mg/m <sup>2</sup> /dose by intravenous infusion every three weeks. There is no dose overlap between the products.
Zetia (Ezetimibe) Tablets, 10 mg <u>Usual Dose:</u> One tablet by mouth once a day	<u>Orthographic:</u> Both have the same beginning letter strings ‘Zet’ <u>Strength:</u> Both single strength products and therefore strength may be omitted <u>Usual Dose:</u> Both are once daily	<u>Orthographic:</u> The ending letter strings appear different when scripted ‘nna’ and ‘tia’. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5 <sup>th</sup> and 6 <sup>th</sup> position and it has a total of 7 letters vs. Zetia has only 5 letters.

<b>Proposed name:</b> <b>Zetonna</b>	<b>Strength(s):</b> <b>37 mcg per actuation</b>	<b>Usual dose:</b> <b>One spray into each nostril daily</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Zelnorm (Tegaserod) Tablets, 2 mg and 6 mg</p> <p>(Note: Product withdrawn from the market on March 30, 2007 and no generic equivalents available)</p> <p><u>Usual Dose:</u> 4 mg to 12 mg by mouth once daily</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings ‘Zet’ and ‘Zel’</p> <p><u>Usual Dose:</u> Both are once daily</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘norm’. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5<sup>th</sup> and 6<sup>th</sup> position</p> <p><u>Strength:</u> Single strength which may be omitted from the prescription versus Multiple strengths which would have to be listed on the prescription. No strength or dose overlap.</p>
<p>Xeloda (Capecitabine) Tablets, 150 mg and 500 mg</p> <p><u>Usual Dose:</u> One tablet by mouth twice a day</p>	<p><u>Orthographic:</u> When scripted ‘Z’ and ‘X’ may look similar therefore they have similar beginning letter strings, ‘Zet’ and ‘Xel’</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘loda’. Zetonna has one upstroke letter vs. Xeloda has two which would give the names a different shape when scripted. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5<sup>th</sup> and 6<sup>th</sup> position.</p> <p><u>Strength:</u> Single strength which may be omitted from the prescription versus Multiple strengths which would have to be included on the prescription. No strength or dose overlap.</p>
<p>Makena (Hydroxyprogesterone Caproate) Injection, 250 mg/mL</p> <p><u>Usual Dose:</u> Administer 250 mg intramuscularly once weekly between 16 weeks, 0 days and 20 weeks, 6 days gestation. Continue once weekly until week 37 of gestation or delivery, whichever comes first</p>	<p><u>Orthographic:</u> The letters ‘Z’ and ‘M’ may look similar when scripted. Both have an upstroke in the same position and similar ending letter strings ‘nna’ and ‘ena’.</p> <p><u>Strength:</u> Both single strength products and therefore strength may be omitted</p>	<p><u>Orthographic:</u> The ending letter strings appear different when scripted ‘onna’ and ‘norm’. Zetonna appears longer when scripted due to the presence of the ‘nn’ in the 5<sup>th</sup> and 6<sup>th</sup> position</p> <p><u>Dosage form, Route of administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Makena which is an injection administered as 250 mg intramuscularly once weekly between 16 weeks, 0 days and 20 weeks, 6 days gestation. Continue once weekly until week 37 of gestation or delivery, whichever comes first. There is no dose overlap between the products.</p>

<b>Proposed name:</b> <b>Zetonna</b>	<b>Strength(s):</b> <b>37 mcg per actuation</b>	<b>Usual dose:</b> <b>One spray into each nostril daily</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
Retavase (Retepase) Kit, 18.1 mg  <u>Usual Dose:</u> Administered as two unit bolus injections for a complete treatment. Each bolus is administered as an intravenous injection over 2 minutes	<u>Orthographic:</u> When scripted 'Z' and 'R' may look similar therefore they have similar beginning letter strings, 'Zet' and 'Ret'  <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Orthographic:</u> The ending letter strings appear different when scripted 'onna' and 'vase'. Zetonna appears longer when scripted due to the presence of the 'nn' in the 5 <sup>th</sup> and 6 <sup>th</sup> position  <u>Usual Dose:</u> Zetonna is administered as one spray into each nostril daily versus Retavase which is administered as two unit bolus injections for a complete treatment. Each bolus is administered as an intravenous injection over 2 minutes. There is no dose overlap.  <u>Storage:</u> Room Temperature vs. Refrigeration
Cetacaine (Benzocaine, Butamben, and Tetracaine hydrochloride) 14%/2%/2%  Topical Gel Topical Spray Topical Liquid  <u>Usual Dose:</u> Applied for approximately one second or less for normal anesthesia.	<u>Orthographic:</u> When scripted 'Z' and 'C' may look similar making the beginning letter strings, 'Zet' and 'Cet' similar  <u>Strength:</u> Both single strength products and therefore strength may be omitted	<u>Orthographic:</u> The letter strings following the upstroke appear different when scripted 'onna' vs. 'acaine'. Zetonna has 7 letters vs. 9 letters in Cetacaine and appears shorter when scripted.  <u>Dosage Form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Cetacaine which is a spray, gel, or liquid applied topically for normal anesthesia.
Sonata (Zaleplon) Capsules, 5 mg and 10 mg  <u>Usual Dose:</u> 5 mg to 10 mg at bedtime	<u>Phonetic:</u> Both names have three syllables. similar beginning letter sounds Both names begin with similar sounding phonemes 's' and 'z' (fricative/alveolar). The ending vowel sound 'a'.  <u>Frequency of administration:</u>  Both products are dosed once daily	<u>Phonetic:</u> The vowel sound in the first syllable is different ('e' vs. 'o'). Although both names have a syllable that begins with the letter 't', they are in different positions (second syllable vs. third). Although both names have a syllable that begins with the letter 'n', they are in different positions (third syllable vs. second).  <u>Strength:</u> Single strength which may be omitted from the prescription versus Multiple strengths which would have to be included on the prescription. No strength or dose overlap.  <u>Dosage Form, Route of Administration, Usual Dose:</u> Zetonna is a nasal aerosol administered as one spray into each nostril daily versus Sonata which is a capsule administered as one to two capsules at bedtime.

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/s/  
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CARLOS M MENA-GRILLASCA on behalf of LISSA C OWENS  
01/12/2012

CARLOS M MENA-GRILLASCA  
01/12/2012

CAROL A HOLQUIST  
01/12/2012

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

**Proprietary Name Review**

Date: October 21, 2011

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

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

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

Drug Name & Strength: (b) (4) (Ciclesonide) Nasal Aerosol  
37 mcg per actuation

Application Type/Number: NDA 202129

Applicant/sponsor: Sunovion Pharmaceuticals Inc.

OSE RCM #: 2011-2623

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/s/  
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LISSA C OWENS  
10/21/2011

CARLOS M MENA-GRILLASCA  
10/21/2011

CAROL A HOLQUIST  
10/21/2011