

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**125431Orig1s000**

**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: August 2, 2013

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

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Drug Name and Strength(s): Tanzeum  
Albiglutide  
Injection  
30 mg and 50 mg

Application Type/Number: BLA 125431

Applicant/Sponsor: GlaxoSmithKline

OSE RCM #: 2013-1201

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

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## 1 INTRODUCTION

This review assesses the promotional and safety aspects of the proposed proprietary name, Tanzeum for BLA 125431, Albiglutide, 30 mg/0.5 mL and 50 mg/0.5 mL injection. This is the fourth proposed name for this product. The previous three proposed proprietary names were rejected for safety reasons (OSE Reviews #2010-1153, #2012-914, and #2013-277). The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the May 15, 2013 proprietary name submission.

- Active Ingredient: Albiglutide
- Indication of Use: GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus
- Route of Administration: subcutaneous injection
- Dosage Form: powder for injection
- Strength: 30 mg, 50 mg
- Dose and Frequency: 30 mg once weekly, may increase to 50 mg once weekly
- How Supplied:
  - 30 mg single-dose pen:
    - carton of 1 (containing one 29-gauge, thinwall needle)
    - carton of 4 (containing four 29-gauge, thinwall needles)
  - 50 mg single-dose pen:
    - carton of 1 (containing one 29-gauge, thinwall needle)
    - carton of 4 (containing four 29-gauge, thinwall needles)
- Storage: Refrigerate at 36° F to 46°F (2°C to 8°C).
- Container and Closure Systems: The container closure system for albiglutide drug product 30 mg and 50 mg consists of a Dual Chamber Cartridge (DCC) as the primary packaging system that is assembled into a pen injector delivery device. The DCC is composed of a Type 1 glass barrel seale (b) (4)

[REDACTED]

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

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

### 2.2 SAFETY ASSESSMENT

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

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

There are no United States Adopted Name (USAN) stems present in the proposed proprietary name.<sup>1</sup>

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

The Applicant indicated in their submission that the proposed name, Tanzeum, is not derived from any characteristic of this or any other drug in particular. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

#### 2.2.3 *FDA Name Simulation Studies*

Seventy-eight 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. Nineteen of the 26 inpatient participants responded correctly and the most common misinterpretation occurred with 5 participants misinterpreting the letter 'u' for 'ri' (i.e. TanzeUm misinterpreted as 'TanzeRIm'). One of the 23 voice participants responded correctly and a common misinterpretation occurred with 20 participants misinterpreting the letter 'e' for 'i' (i.e. TanzEum misinterpreted as 'TanzIum'). Two of the 29 outpatient participants responded correctly and the most common misinterpretation occurred with 23 participants misinterpreting the letter 'z' for 'g' (i.e. TanZum misinterpreted as 'TanG'). 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.

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<sup>1</sup> July 8, 2013 search of the United States Adopted Name (USAN) stems

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

In response to the OSE, May 28, 2013 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) 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 Name

Appendix B lists the possible orthographic and phonetic misinterpretations of the letters considered in the search for similar names to Tanzeum. Table 1 lists the names identified by the primary reviewer, Expert Panel Discussion (EPD), other review disciplines, and the (b) (4) to have potential orthographic, phonetic, or spelling similarity to the proposed proprietary name. Our analysis 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, Expert Panel Discussion (EPD), Other Disciplines, and External Name Study)</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
<b>Look Similar</b>					
Fempain	RB/EPD	Teczem	FDA/EPD	Lorcaserin	AC/EPD
Tanafed	CP/EPD	Teniposide	CP/EPD	Tazorac	AC/EPD
Femiron	AM/EPD	Linzess	AC/EPD	Tenormin	AC/EPD
Terazosin	AC/EPD	Tiopronin	AC/EPD	Fosteum	(b) (4)
Testim	AM/EPD	Toposar	FDA/EPD	Tegaderm	WG/EPD
Tannicum (Acidum)	RB/EPD	Tinaderm	RB/EPD	Trizivir	MM/EPD
Tenivac	LC/SE	Zanamivir	LC/SE	Tasigna	LC/EPD
Tarceva	FDA/EPD	Tasmar	FDA/EPD	Tencon	CP/EPD
Fragmin	LC/EPD	Tandem (DHA, OB)	(b) (4) EPD	Tarsum	(b) (4) EPD
Kadian	(b) (4)	Nexium	(b) (4)	Tamoxifen	(b) (4)
Tekturna	(b) (4)	Tinidazole	(b) (4)	Valium	(b) (4)
Fuzeon	EPD				
<b>Look and Sound Similar</b>					
Tanzeum	USPTO	Tensium	Saegis		

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

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on July 8, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on July 9, 2013, they stated no additional concerns with the proposed proprietary name, Tanzeum.

## **3 CONCLUSIONS**

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

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

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

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the BLA. The results are subject to change. If any of the proposed product characteristics as stated in your May 15, 2013 submission are altered, 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. *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>2</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>2</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>3</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>3</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>4</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>4</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.

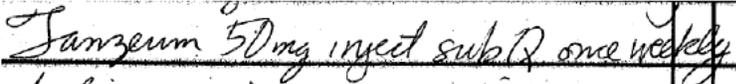
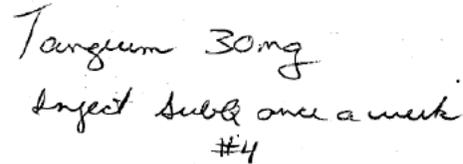
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Tanzeum	Scripted May Appear as	Spoken May Be Interpreted as
'T'	F, Z, J	D
lowercase 't'	r, f, x, a	D
lowercase 'a'	el, ci, cl, d, o, u	Any vowel
lowercase 'n'	m, u, x, r, h, s	dn, gn, kn, mn
Lowercase 'z'	c, e, g, n, m, q, r, s, v	c, s, x
lowercase 'e'	a, I, l, o, u, p	Any vowel
lowercase 'u'	n, y, v, w, a, e, i, o	Y
lowercase 'm'	rn, nn, n, v, w, wi, vi, onc, z	ee, i
Letter Strings		
'ze'	U	
'eu'	W	

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

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Tanzeum 30 mg Inject subq once a week #4</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

**Study Name: Tanzeum**

As of Date 6/25/2013

191 People Received Study

78 People Responded

Study Name: Tanzeum

	<b>Total</b>	<b>29</b>	<b>23</b>	<b>26</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>	
???	1	0	0	1	
FANZEUM	0	0	1	1	
TAMVIAM	0	1	0	1	
TAMZYEM	0	1	0	1	
TANGEUM	2	0	0	2	
TANGIUM	13	0	0	13	
TANGLUM	3	0	0	3	
TANGRUM	1	0	0	1	
TANGUEM	2	0	0	2	
TANGUM	2	0	0	2	
TANSIUM	0	2	0	2	
TANZERIM	0	0	5	5	
TANZERUM	0	0	1	1	
TANZEUM	2	1	18	21	
TANZEUM INJECTIBLE	0	0	1	1	
TANZIUM	2	17	0	19	
TANZUIM	0	1	0	1	
TAZELIUM	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 Tanzeum	Failure preventions
1	<b>Tanzeum</b>	Albiglutide	Look and Sound alike	This name is the subject of this review.
2	<b>Fempain</b>	Acetaminophen, Cinnamedrine HCl, Pamabrom, and Pyrilamine	Look alike	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
3	<b>Tannicum Acidum</b>	Homeopathic Substance	Look alike	Name identified in USPTO (Johnson and Johnson). Unable to find product characteristics in commonly used drug databases.
4	<b>Teczem</b>	Diltiazem and Enalapril	Look alike	Product withdrawn FR Effective July 8, 2011. No generic available.
5		<b>Teniposide</b>	Look alike	The pair have sufficient orthographic differences
4		<b>Tiopronin</b>	Look like	The pair have sufficient orthographic differences
5	<b>Toposar</b>	Etoposide	Look alike	The pair have sufficient orthographic differences
6	<b>Tinaderm</b>	Tolnaftate	Look alike	International product marketed in Europe
7		<b>Lorcaserin</b>	Look alike	The pair have sufficient orthographic differences
8	<b>Tegaderm</b>	Wound dressing	Look alike	The pair have sufficient orthographic differences
9	<b>Kadian</b>	Morphine Sulfate	Look alike	The pair have sufficient orthographic differences
10	<b>Tekturna</b>	Aliskiren Fumarate	Look alike	The pair have sufficient orthographic differences
11	<b>Nexium</b>	Esomeprazole	Look alike	The pair have sufficient orthographic differences
12		<b>Tinidazole</b>	Look alike	The pair have sufficient orthographic differences

13		<b>Tamoxifen</b>	Look alike	The pair have sufficient orthographic differences
14	<b>Valium</b>	Diazepam	Look	The pair have sufficient orthographic differences
15	<b>Fragmin</b>	Dalteparin Sodium	Look	The pair have sufficient orthographic differences

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

	Proposed name: <i>Tanzeum</i> (Albiglutide) <b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg <b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.	<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> <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
1	<b>Tarceva</b> (Erlotinib) <b>Dosage form and Strength(s):</b> Oral tablet: 25 mg, 100 mg, 150 mg <b>Usual dose:</b> One tablet by mouth 1 hour before or 2 hours after food	<b>Orthographic similarity:</b> Both names begin with the letter 'T' and the letter strings 'anzeu' and 'arcev' appear orthographically similar when scripted.  thus an order for these products will require strength for a complete prescription.	<b>Orthographic difference:</b> The ending letter 'm' and 'a' appear orthographically different when scripted.  <b>Frequency:</b> Tanzeum is prescribed weekly vs. Tarceva is prescribed daily.

	Proposed name: <i>Tanzeum</i> (Albiglutide) <b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg <b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.	<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> <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
2	<b>Tarsum</b> (Coal tar and salicylic acid) <b>Dosage form and Strength(s):</b> External gel (shampoo): 2% <b>Usual dose:</b> Apply to wet hair; massage into scalp; rinse once a week or up to once daily	<b>Orthographic similarity:</b> Both names begin with the letter string 'Ta' and end with the letter string 'um.' In addition, letter strings 'nze' and 'rsu' appear orthographically similar when scripted. <b>Frequency:</b> Both may be prescribed as weekly	<b>Strength:</b> Multiple vs. single. There is no numerical overlap or similarity between the strengths.
3	<b>Fosteum</b> (Ganistein, Amino acid chelates, Cholecalciferol) <b>Dosage form and Strength(s):</b> Oral capsules: 27 mg/20 mg/200 Int. Units <b>Usual dose:</b> One to two capsules by mouth daily	<b>Orthographic similarity:</b> The letter strings 'Tan' and 'Fos' appear orthographically similar when scripted. In addition, both names end with the letter string 'eum'	<b>Orthographic difference:</b> The letters 'z' and 't' appear orthographically different when scripted. <b>Strength:</b> Multiple vs. single. An order for Tanzeum will require strength as it is available in multiple strengths vs. Fosteum is available as a fixed-dose single strength tablet and may be omitted. There is no numerical overlap or similarity between the strengths. <b>Frequency:</b> Tanzeum is prescribed weekly vs. Fosteum is prescribed daily.

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Femiron</b> (Iron)</p> <p><b>Dosage form and Strength(s):</b> Oral tablet: 20 mg</p> <p><b>Usual dose:</b> 2 to 3 mg/kg daily divided into 3 doses. Based on a 70 kg adult, dose is 140 mg to 210 mg per day.</p>	<p><b>Orthographic similarity:</b> The beginning letter strings ‘Tan’ / ‘Fem’ and the ending letter strings ‘zeum’ / ‘iron’ appear orthographically similar when scripted.</p>	<p><b>Strength:</b> Multiple vs. single. An order for Tanzeum will require strength as it is available in multiple strengths vs. Femiron is available in single strength and may be omitted. There is no numerical overlap or similarity between the strengths.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Femiron is prescribed 3 times a day.</p>
5	<p><b>Terazosin</b></p> <p><b>Dosage form and Strength(s):</b> Oral capsules: 1 mg, 2 mg, 5 mg, 10 mg</p> <p><b>Usual dose:</b> One tablet by mouth at bedtime</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and the beginning letter strings ‘an’ and ‘er’ appear orthographically similar when scripted.</p> <p><b>Strength:</b> Both are available in multiple strengths and there is numerical overlap or similarity between the strengths (50 mg vs. 5 mg)</p>	<p><b>Orthographic difference:</b> Tanzeum (7 letters) appear orthographically shorter than Terazosin (9 letters) when scripted. In addition, the ending letter strings ‘zeum’ and ‘azosin’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Terazosin is prescribed daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Tanafed DMX*</b> (Dextromethorphan HBr, Dexchlorpheniramine, and Pseudoephedrine)</p> <p><b>Dosage form and Strength(s):</b> Oral suspension: 2.5 mg/25 mg/75 mg per 5 mL</p> <p><b>Usual dose:</b> 2.5 mL to 20 mL by mouth every 12 hours not to exceed 40 mL in 24 hours</p> <p><b>Tanafed DP</b> (Dexchlorpheniramine and Pseudoephedrine)</p> <p><b>Dosage form and Strength(s):</b> Oral suspension: 2.5 mg/75 mg per 5 mL</p> <p><i>* Product is discontinued.</i></p>	<p><b>Orthographic similarity:</b> Both names begin with the letter string ‘Tan’</p> <p><b>Dose:</b> There is numerical overlap between doses (30 mg vs. 30 mL)</p>	<p><b>Orthographic difference:</b> Tanafed contains an upstroke/downstroke ‘f’ in position 5 and ends with an upstroke ‘d’ which is absent in Tanzeum, giving the names different shapes and making the ending letter strings ‘zeum’ and ‘afed’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Both may be prescribed as twice daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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>
7	<p><b>Testim</b> (Testosterone)</p> <p><b>Dosage form and Strength(s):</b> Transdermal gel: 1%</p> <p><b>Usual dose:</b> 5 g (to deliver testosterone 50 mg) applied once daily (preferably in the morning) to clean, dry, intact skin of the shoulders and/or upper arms</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and end with letter ‘m’</p> <p><b>Strength and Dose:</b> There is a numerical similarity between the strength for Tanzeum (50 mg) vs. the dose for Testim (5 gm).</p>	<p><b>Orthographic difference:</b> The letter strings ‘anzeu’ and ‘esti’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Testim is prescribed daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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>
8	<p><b>Tenivac</b> (Diphtheria Toxoid and Tetanus Toxoid)</p> <p><b>Dosage form and Strength(s):</b> Intramuscular injectable: 2 LFU and 5 LFU</p> <p><b>Usual dose:</b> Primary immunization: Three 0.5 mL IM doses. The first 2 doses are administered 2 months apart and the third dose is administered 6 to 8 months after the second dose. The interval between doses recommended by the ACIP is 4 to 8 weeks between the first and second dose and 6 to 12 months between the second and third dose</p> <p>Booster: 0.5 mL intramuscularly every 10 years</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and the letter strings ‘an’ and ‘en’ appear orthographically similar when scripted.</p> <p><b>Dosage form and route of administration:</b> Both are available as parenteral injection</p>	<p><b>Orthographic difference:</b> The ending letter strings ‘zeum’ and ‘ivac’ appear orthographically different when scripted.</p> <p><b>Strength:</b> Multiple vs. NO strength. An order for Tanzeum will require strength as it is available in multiple strengths vs. Tenivac does not have a strength.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tenivac is prescribed once.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Linzess</b> (Linaclotide)</p> <p><b>Dosage form and Strength(s):</b> Oral capsule: 145 mcg and 290 mcg</p> <p><b>Usual dose:</b> One capsule by mouth daily</p>	<p><b>Orthographic similarity:</b> Both names contain the letter string ‘nze’ in similar positions and then ending letter strings ‘um’ and ‘ss’ appear orthographically similar when scripted.</p>	<p><b>Orthographic difference:</b> The beginning letter string ‘Ta’ and ‘Li’ appear orthographically different when scripted.</p> <p><b>Strength:</b> Both are available in multiple strengths, thus an order for these products will require strength for a complete prescription. There is no numerical overlap or similarity between the strengths.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Linzess is prescribed daily.</p>
10	<p><b>Zanamivir</b> (<i>Relenza Diskhaler</i>)</p> <p><b>Dosage form and Strength(s):</b> Aerosol powder breath activated for Inhalation: 5 mg per blister</p> <p><b>Usual dose:</b> 10 mg (2 inhalations) once daily</p>	<p><b>Orthographic similarity:</b> The beginning letter strings ‘Tan’ and ‘Zan’ appear orthographically similar when scripted.</p> <p><b>Strength:</b> There is numerical overlap or similarity between the strengths (50 mg vs. 5 mg)</p>	<p><b>Orthographic difference:</b> Tanzeum (7 letters) appear orthographically shorter than Zanamivir (9 letters) when scripted. In addition, the ending letter strings ‘zeum’ and ‘amivir’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Zanamivir is prescribed daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Tasmar</b> (Tolcapone)</p> <p><b>Dosage form and Strength(s):</b> Oral tablet: 100 mg</p> <p><b>Usual dose:</b> One tablet by mouth 3 times daily, always an adjunct to levodopa/carbidopa.</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘Ta’ and the letter strings ‘nze’ and ‘sma’ appear orthographically similar when scripted.</p>	<p><b>Orthographic difference:</b> Tanzeum contains an additional letter ‘m’, making the ending letter strings ‘um’ and ‘r’ appear orthographically different when scripted.</p> <p><b>Strength:</b> Multiple vs. single. An order for Tanzeum will require strength as it is available in multiple strengths vs. Tasmar is available in single strength and may be omitted. There is no numerical overlap or similarity between the strengths.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tasmar is prescribed 3 times a day.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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>
12	<p><b>Tandem*</b> (Prenatal Vitamins and Minerals with Iron, Folic Acid, and Omega-3 Fatty Acids)</p> <p><b>Dosage form and Strength(s):</b> Oral tablet or capsules</p> <p><b>Usual dose:</b> One tablet by mouth daily</p> <p><i>*Available in multiple formulations (-F, -OB, -DHA, and -Plus)</i></p>	<p><b>Orthographic similarity:</b> Both names begin with the letter string ‘Tan’ and end with the letter ‘m.’</p>	<p><b>Orthographic difference:</b> Tandem contains an upstroke ‘d’ in position 4 which is absent in Tandem, giving the names different shapes. In addition, Tandem is available in different formulations (-F, -OB, -DHA, -Plus) requiring the use of a modifier for a complete prescription.</p> <p><b>Strength:</b> Multiple vs. No strength. An order for Tanzeum will require strength as it is available in multiple strengths vs. Tandem does not have a strength.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tandem is prescribed daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Tenormin</b> (Atenolol)</p> <p><b>Dosage form and Strength(s):</b> Oral tablet: 25 mg, 50 mg, 100 mg</p> <p><b>Usual dose:</b> One tablet by mouth daily or twice daily.</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and the letter strings ‘an’ / ‘en’ and ending letters ‘m’ / ‘n’ appear orthographically similar when scripted.</p> <p><b>Strength:</b> Both are available in multiple strengths, thus an order for these products will require strength for a complete prescription. There is numerical overlap between the strengths (50 mg).</p>	<p><b>Orthographic difference:</b> The letter string ‘zeu’ appear orthographically shorter and different from ‘ormi’ when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tenormin is prescribed once or twice daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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	<p><b>Tazorac</b> (Tazarotene)</p> <p><b>Dosage form and Strength(s):</b> External cream and gel: 0.05% and 0.1%</p> <p><b>Usual dose:</b> Cleanse the face gently. After the skin is dry, apply a thin film of tazarotene (2 mg/cm<sup>2</sup>) once a day in the evening to the skin where lesions appear. Use enough to cover the entire affected area.</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘Ta’ and the letter ‘z’ and ‘n’ appear orthographically similar when scripted.</p>	<p><b>Orthographic difference:</b> The ending letter strings ‘eum’ and ‘orac’ appear orthographically different when scripted.</p> <p><b>Strength:</b> Both are available in multiple strengths, thus an order for these products will require strength for a complete prescription. There is no numerical overlap or similarity between the strengths.</p> <p><b>Dose:</b> Inject subcutaneously vs. apply to face</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tazorac is prescribed daily.</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Trizivir</b> (Abacavir, Lamivudine, and Zidovudine)</p> <p><b>Dosage form and Strength(s):</b> Oral tablets: 300 mg/150 mg/300 mg</p> <p><b>Usual dose:</b> One tablet by mouth twice daily</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and the ending letter strings ‘zeum’ and ‘zivir’ appear orthographically similar when scripted.</p>	<p><b>Orthographic difference:</b> The letter string ‘an’ and ‘ri’ appear orthographically different when scripted.</p> <p><b>Strength:</b> Multiple vs. single. An order for Tanzeum will require strength as it is available in multiple strengths vs. Trizivir is available as a fixed-dose single strength tablet and may be omitted. There is no numerical overlap or similarity between the strengths.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Trizivir is prescribed twice daily</p>
16	<p><b>Tasigna</b> (Nilotinib)</p> <p><b>Dosage form and Strength(s):</b> Oral capsule: 150 mg and 200 mg</p> <p><b>Usual dose:</b> 2 capsules by mouth twice daily</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘Ta’ and the letter ‘z’ when scripted with a downstroke appear orthographically similar with the letter ‘g’</p>	<p><b>Orthographic difference:</b> The ending letter strings ‘eum’ and ‘na’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Terazosin is prescribed twice daily.</p> <p><b>Strength:</b> Both are available in multiple strengths and there is no overlap in strengths</p>

	<p>Proposed name: <i>Tanzeum</i> (Albiglutide)</p> <p><b>Dosage form and Strength(s):</b> Lyophilized powder, reconstituted for subcutaneous injection: 30 mg, 50 mg</p> <p><b>Usual dose:</b> Inject 30 mg subcutaneously once weekly, may increase to 50 mg once weekly.</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><b>Tencon</b> (Acetaminophen and Butalbital)</p> <p><b>Dosage form and Strength(s):</b> Oral capsules: 650 mg/50 mg</p> <p><b>Usual dose:</b> One capsule by mouth every 4 hours as needed, not to exceed 6 capsules per day.</p>	<p><b>Orthographic similarity:</b> Both names begin with the letter ‘T’ and the letter strings ‘anz’ and ‘enc’ appear orthographically similar when scripted.</p> <p><b>Strength:</b> The acetaminophen strength may be omitted, thus the Butalbital component may be used alone during prescription writing, giving a numerical overlap between the strengths (50 mg vs. 650 mg/50 mg).</p>	<p><b>Orthographic difference:</b> The ending letter strings ‘eum vs. ‘on’ appear orthographically different when scripted.</p> <p><b>Frequency:</b> Tanzeum is prescribed weekly vs. Tencon is prescribed every 4 hours as needed.</p>
18	<p><b>Fuzeon</b> (Enfuvirtide)</p> <p><b>Dosage form and Strength(s):</b> Solution reconstituted and Kit for Subcutaneous Injection: 90 mg</p> <p><b>Usual dose:</b> 90 mg twice daily</p>	<p><b>Orthographic similarity:</b> The beginning letter strings ‘Ta’ / ‘Fu’ and ending letter strings ‘zeum’ / ‘zeon’ appear orthographically similar when scripted.</p> <p><b>Dosage form and route of administration:</b> Both are available as solution given subcutaneously.</p>	<p><b>Orthographic difference:</b> Tanzeum contains an additional letter ‘n’ making it appear orthographically longer than Fuzeon when scripted.</p> <p><b>Strength:</b> Multiple vs. single. An order for Tanzeum will require strength as it is available in multiple strengths vs. Fuzeon is available in single strength and may be omitted. There is no numerical overlap or similarity between the strengths.</p>

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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REASOL AGUSTIN  
08/01/2013

YELENA L MASLOV  
08/02/2013

CAROL A HOLQUIST  
08/02/2013

**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: April 12, 2013

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Drug Name and Strength: Eperzan  
(Albiglutide)  
Injection  
30 mg and 50 mg

Application Type/Number: BLA 125431

Applicant/Sponsor: GlaxoSmithKline

OSE RCM #: 2013-277

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Eperzan, 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 PRODUCT INFORMATION

The following product information is provided in the January 11, 2013 proprietary name submission.

- Active Ingredient: Albiglutide
- Indication of Use: GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus
- Route of Administration: subcutaneous injection
- Dosage Form: powder for injection
- Strength: 30 mg, 50 mg
- Dose and Frequency: 30 mg once weekly, may increase to 50 mg once weekly
- How Supplied:
  - 30 mg single-dose pen:  
carton of 1 (containing one 29-gauge, thinwall needle)  
carton of 4 (containing four 29-gauge, thinwall needles)
  - 50 mg single-dose pen:  
carton of 1 (containing one 29-gauge, thinwall needle)  
carton of 4 (containing four 29-gauge, thinwall needles)
- Storage: Refrigerate at 36° F to 46°F (2°C to 8°C).
- Container and Closure Systems: The container closure system for albiglutide drug product 30 mg and 50 mg consists of a Dual Chamber Cartridge (DCC) as the primary packaging system that is assembled into a pen injector delivery device. The DCC is composed of a Type 1 glass barrel sealed (b) (4)

## 2. RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

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

## 2.2 SAFETY ASSESSMENT

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

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

The March 1, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

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

The Applicant indicated in their submission that the proposed name, Eperzan, is not derived from any characteristics of this or any other drug in particular. 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.

### 2.2.4 *FDA Name Simulation Studies*

Eighty-one practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the interpretations look or sound like any marketed products or products in the pipeline. Thirty-seven participants correctly identified the name as Eperzan. The most frequent misinterpretations was the last letter 'n' as an 'm'. Other notable misinterpretations included the letter 'z' for 'g' or 'j'. We considered these deviations in our assessment of the proposed proprietary name, Eperzan. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### 2.2.5 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, February 11, 2013 e-mail, the DMEP did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

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

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

<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Apriso	(b) (4)	Eperbel-S	FDA	Epivir	FDA

<b>Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)</b>					
Apiscare	FDA	Eperzanel	FDA	Epzicom	FDA
Aplenzin	FDA	Epicare	FDA	Excedrin	(b) (4)
<b>Look Similar</b>					
Endocet	(b) (4)	Epifoam	FDA		
Epa-Con	FDA	Epiform-HC	FDA		
<b>Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Efavirez	(b) (4)	Operand	(b) (4)		
<b>Look and Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Eperzan	FDA	Eperisone	FDA	Epifrin	FDA/ (b) (4)
Aspercin	(b) (4)	Eperzane	FDA	Epipen	FDA/ (b) (4)
Aspirin	(b) (4)	Eperzant	FDA	Epogen	FDA/ (b) (4)
Enbrel	(b) (4)	EpiCeram	FDA/ (b) (4)	Mepergan	(b) (4)

Our analysis of the 27 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that 26 names identified will not pose a risk for confusion as described in Appendix D and E. However, the proposed name could be confused with Epogen. The rationale for the risk of confusion is described in section 3.1.

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

DMEPA communicated our findings to the DMEP via e-mail on March 28, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on March 28, 2013, they stated no additional concerns with the proposed proprietary name, Eperzan.

## **3 CONCLUSIONS**

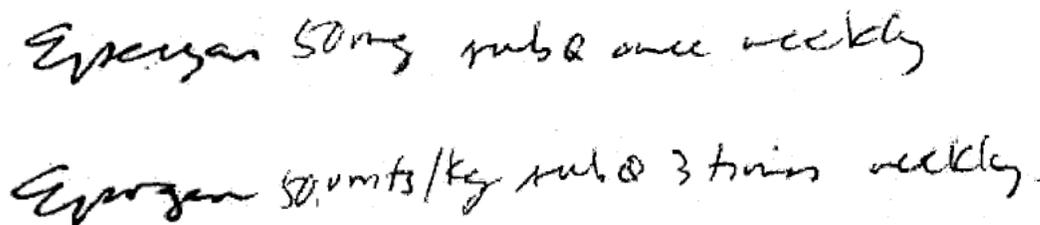
The proposed proprietary name is acceptable from a promotional perspective but not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with the currently marketed product, Epogen. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See section 3.1).

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

### 3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Eperzan, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Eperzan, is orthographically similar to and shares overlapping product characteristics with the currently marketed product, Epogen (epoetin alfa). The orthographic similarity stems from the similar length and shape (7 vs. 6 letters and 2 down strokes) of the names, and similar appearance of the letters comprising the name when scripted. Each name begins with the letter string 'Ep' and ends with the letter strings 'zan' and 'gen' that appear similar when scripted (down stroked 'z' may look like 'g' and 'an' may look like 'en'). Although Eperzan has two letters in the infix, 'er' compared to the 'o' in Epogen, if 'er' is scripted without much rounding or elongation, the length of the two letters may be similar to that of the letter 'o' (See example below).



The image shows two handwritten prescriptions. The first line reads "Eperzan 50mg subQ once weekly". The second line reads "Epogen 50 units/kg subQ 3 times weekly". The handwriting is cursive and somewhat slanted, illustrating the orthographic similarity between the two names when written.

Moreover, the pair shares overlapping product characteristics such as dosage form (solution for injection) and route of administration (subcutaneous injection). Additionally, the products share similarity in doses (i.e., 50 mg vs. 50 units), therefore a prescription for "Eperzan 50 mg" could be confused with "Epogen 50 units/kg" if the units of measure are misinterpreted or the word "units" is not fully written. We have identified post-marketing reports of confusion between products with different units of measure when orthographic similarity exists. As an example, a report from ISMP describes confusion between Lovenox 30 mg and Levemir 30 units. This error occurred despite the differences in units of measurement. In the case of Eperzan and Epogen, the differences in units of measure may not be sufficient to prevent a wrong drug error from occurring and the numerical overlap in the dose may also contribute to medication errors. The differences in frequency of administration (once weekly vs. 3 times weekly) may not provide sufficient differentiation considering the strong orthographic similarity and other common product characteristics.

Your external name evaluation also identified Epogen as a name with potential similarities to Eperzan. However, (b) (4) stated that "Epogen shares an overlapping dosage form/route of administration with EPERZAN, but differs significantly with respect to dosage strength, frequency of administration, and usual dose, thereby significantly minimizing the risk for confusion and error between the names in clinical practice." However, as stated above, the dose overlaps numerically (50 mg vs. 50 units/kg) and the

frequency contains the weekly dosing schedule, thus there is a risk of confusion and error between the two names in the presence of a strong orthographic similarity between the names as described above. Thus, based on the similarity of the names and the shared product characteristics, we conclude that the orthographic similarity and overlapping product characteristics creates a potential for confusion between Eperzan and Epogen that may lead to wrong drug errors.

## 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 ([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.

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 ([www.medilexicon.com](http://www.medilexicon.com))**

Medical Abbreviations dictionary 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.

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

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

## APPENDICES

### Appendix A

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

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

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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.

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

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

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<sup>3</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

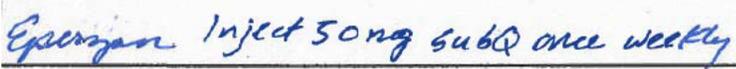
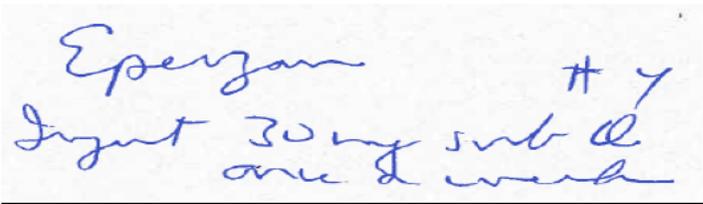
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Eperzan	Scripted May Appear as	Spoken May Be Interpreted as
E	C, f	any vowel
e	a, i, o, u	
p	yn, ys, g, j, l, q	b
r	e, n, s, v	
z	c, e, g, j, n, m, q, r, s, v	c, j, s, x
a	el, ci, cl, d, o, u	any vowel
n	m, u, x, r, h, s	dn, gn, kn, mu, pu
Letter Strings	Scripted May Appear as	Spoken May Be Interpreted as
er	u	

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

**Figure 1. Eperzan Study (Conducted on 2/4/2013)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Eperzan Inject 30 mg subcutaneously once a week #4</p>
<p><u>Outpatient Prescription:</u></p> 	

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

**Study Name: Eperzan**

192 People Received Study

81 People Responded

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
APERSAM	0	1	0	1
APPERZIM	0	1	0	1
EPEGAM	0	0	1	1
EPEGOM	0	0	1	1
EPEIZAN	0	0	1	1
EPERGAN	0	0	4	4
EPERJAN	0	0	1	1
EPERSAM	0	1	0	1
EPERSAYM	0	1	0	1
EPERZAM	0	5	5	10
<b>EPERZAN</b>	<b>27</b>	<b>4</b>	<b>6</b>	<b>37</b>
EPERZAN INJECT	1	0	0	1
EPERZIM	0	1	0	1
EPERZON	1	0	1	2
EPEZAN	0	0	2	2
EPIJEN	0	0	1	1
EPIRZAM	0	1	0	1
EPIZAN	0	1	1	2
EPOERZAM	0	0	1	1
EPERZAN	0	1	0	1
EPRAZAM	0	2	0	2
EPRAZAN	0	1	0	1
EPRAZEM INJECTION	0	1	0	1
EPREZAN	0	0	1	1
EPRIZAM	0	2	0	2
ESPERZAN	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 Eperzan	Failure preventions
1.	Apexicon	Diflorasone diacetate	Orthographic	The pair has sufficient orthographic differences.
2.	Apiscare	“homeopathic substance”	Orthographic	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
3.	Aplenzin	Bupropion HBr	Orthographic	The pair has sufficient orthographic differences.
4.	Epa-con	Omega-3 fatty acids	Orthographic	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
5.	Eperbel-S	Belladonna alkaloids/ergotamine/phenobarbital	Orthographic	The pair has sufficient orthographic differences.
6.	Eperzanel		Orthographic	Name identified in USPTO. Unable to find product characteristics in commonly used drug databases.
7.	Epi-care	chloroxylenol	Orthographic	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
8.	Epifoam	hydrocortisone/pramoxine	Orthographic	The pair has sufficient orthographic differences.
9.	Epiform- HC	clioquinol/hydrocortisone	Orthographic	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
10.	Eperzan	Albiglutide	Orthographic and Phonetic	Subject of this review.
11.	Eperisone		Orthographic and Phonetic	Name identified in Micromedex. Unable to find product characteristics in commonly used drug databases.

No.	Proprietary Name	Active Ingredient	Similarity to Eperzan	Failure preventions
12.	Eperzane		Orthographic and Phonetic	Name identified in USPTO. Unable to find product characteristics in commonly used drug databases.
13.	Eperzant		Orthographic and Phonetic	Name identified in USPTO. 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><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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>
1.	<p><b>Apriso (mesalamine)</b></p> <ul style="list-style-type: none"> <li>- 0.375 g oral capsules</li> <li>- 4 capsules (1.5 g) once daily</li> <li>- (b) (4)</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘ep’ and ‘ap’ may appear similar when scripted</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erzan’ and ‘riso’ appear different when scripted</li> </ul> <p><b>Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 0.375 g)</li> <li>- Dose (30 mg, 50 mg vs. 1.5 g)</li> </ul>
2.	<p><b>Endocet (oxycodone/acetaminophen)</b></p> <ul style="list-style-type: none"> <li>- 5 mg/325 mg, 7.5 mg/325 mg, 7.5 mg/500 mg, 10 mg/325 mg, 10 mg/650 mg oral tablets</li> <li>- 1 tablet every 6 hours as needed</li> <li>- (b) (4)</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with an ‘E’</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘ndocet’ appear different when scripted</li> </ul> <p><b>Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 5 mg/325 mg, 7.5 mg/325 mg, 7.5 mg/500 mg, 10 mg/325 mg, 10 mg/650 mg)</li> <li>- Dose (30 mg, 50 mg vs. 1 tablet)</li> </ul>

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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>																														
3.	<p><b>Epivir (lamivudine)</b></p> <ul style="list-style-type: none"> <li>- 150 mg, 300 mg oral tablets</li> <li>- 10 mg/mL oral solution</li> <li>- 16 or older: 300 mg daily (150 mg bid or 300 mg qd)</li> <li>- 3 months to 16 years</li> </ul> <table border="1" data-bbox="207 821 656 1203"> <thead> <tr> <th rowspan="2">Weight (kg)</th> <th colspan="2">Dosage Regimen Using Scored 150-mg Tablet</th> <th rowspan="2">Total Daily Dose</th> </tr> <tr> <th>AM Dose</th> <th>PM Dose</th> </tr> </thead> <tbody> <tr> <td>14 to 21</td> <td>½ tablet (75 mg)</td> <td>½ tablet (75 mg)</td> <td>150 mg</td> </tr> <tr> <td>&gt;21 to &lt;30</td> <td>½ tablet (75 mg)</td> <td>1 tablet (150 mg)</td> <td>225 mg</td> </tr> <tr> <td>≥30</td> <td>1 tablet (150 mg)</td> <td>1 tablet (150 mg)</td> <td>300 mg</td> </tr> </tbody> </table> <p><b>Table 2. Adjustment of Dosage of EPIVIR in Adults and Adolescents (≥30 kg) in Accordance With Creatinine Clearance</b></p> <table border="1" data-bbox="207 1377 656 1820"> <thead> <tr> <th>Creatinine Clearance(mL/min)</th> <th>Recommended Dosage of EPIVIR</th> </tr> </thead> <tbody> <tr> <td>≥50</td> <td>150 mg twice daily or 300 mg once daily</td> </tr> <tr> <td>30-49</td> <td>150 mg once daily</td> </tr> <tr> <td>15-29</td> <td>150 mg first dose, then 100 mg once daily</td> </tr> <tr> <td>14-May</td> <td>150 mg first dose, then 50 mg once daily</td> </tr> <tr> <td>&lt;5</td> <td>50 mg first dose, then 25 mg once daily</td> </tr> </tbody> </table>	Weight (kg)	Dosage Regimen Using Scored 150-mg Tablet		Total Daily Dose	AM Dose	PM Dose	14 to 21	½ tablet (75 mg)	½ tablet (75 mg)	150 mg	>21 to <30	½ tablet (75 mg)	1 tablet (150 mg)	225 mg	≥30	1 tablet (150 mg)	1 tablet (150 mg)	300 mg	Creatinine Clearance(mL/min)	Recommended Dosage of EPIVIR	≥50	150 mg twice daily or 300 mg once daily	30-49	150 mg once daily	15-29	150 mg first dose, then 100 mg once daily	14-May	150 mg first dose, then 50 mg once daily	<5	50 mg first dose, then 25 mg once daily	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Epe’ and ‘Epi’ may appear similar when scripted</li> </ul> <p><b>Overlapping Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose (30 mg vs. 300 mg and 50 mg)</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘rz’ and ‘v’ appear different when scripted and makes ‘Eperzan’ appear longer than Epivir</li> </ul>
Weight (kg)	Dosage Regimen Using Scored 150-mg Tablet		Total Daily Dose																														
	AM Dose	PM Dose																															
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No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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><b>Epzicom</b> (abacavir/lamivudine)</p> <ul style="list-style-type: none"> <li>- 600 mg/300 mg oral tablets</li> <li>- 1 tablet once daily</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘Ep’</li> <li>- ‘an’ and ‘om’ may appear similar when scripted</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erz’ and ‘zic’ appear different when scripted</li> </ul> <p><b>Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 600 mg/300 mg)</li> <li>- Dose (30 mg, 50 mg vs. 1 tablet)</li> <li>- Frequency of Administration (once weekly vs. once daily)</li> </ul>
5.	<p><b>Excedrin is a family of products with these modifiers:</b></p> <p>Back and Body (acetaminophen/aspirin): 250 mg/250 mg</p> <p>Extra Strength (acetaminophen/aspirin/caffeine): 250 mg/250 mg/65 mg</p> <p>Menstrual Complete (acetaminophen/aspirin/caffeine): 250 mg/250 mg/65 mg</p> <p>Migraine (acetaminophen/aspirin/caffeine): 250 mg/250 mg/ 65 mg</p> <p>PM (acetaminophen/diphenhydramine): 500 mg/38 mg</p> <p>Tension Headache (acetaminophen/caffeine): 500 mg/65 mg</p> <p>- (b) (4)</p>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘E’</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erz’ and ‘cedr’ appear different when scripted</li> </ul> <p><b>Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. various strengths)</li> <li>- Dose (30 mg, 50 mg vs. 1 tablet)</li> </ul>

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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><b>Aspercín (Aspirin)</b></p> <ul style="list-style-type: none"> <li>- 325 mg oral tablets</li> <li>- 1 tablet 4 to 6 times daily as needed</li> <li>- (b) (4)</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘eg’ and ‘ap’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘E’ and ‘A’ may sound similar when spoken</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘spercín’ appear different when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘spercín’ sound different when spoken</li> </ul> <p><b>Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 325 mg)</li> <li>- Dose (30 mg, 50 mg vs. 1 tablet)</li> </ul>
7.	<p><b>Aspirin</b></p> <ul style="list-style-type: none"> <li>- 81 mg, 325 mg, 500 mg, 600 mg, 650 mg, 975 mg oral tablets</li> <li>- 120 mg, 200 mg, 300 mg, 600 mg rectal suppository</li> <li>- 1 tablet every 4 -6 hours as needed</li> <li>- (b) (4)</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘e’ and ‘a’ may appear similar when scripted</li> <li>- ‘zan’ and ‘rin’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘E’ and ‘A’ may sound similar when spoken</li> </ul> <p><b>Overlapping Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 300 mg, 500 mg)</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘per’ and ‘spi’ appear different when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘spirin’ sound different when spoken</li> </ul>

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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>																	
8.	<p><b>Enbrel (etanercept)</b></p> <ul style="list-style-type: none"> <li>- 25 mg, 50 mg prefilled syringe for subcutaneous injection</li> <li>- 25 mg multiple-use vial</li> <li>- (b) (4)</li> </ul> <table border="1" data-bbox="207 772 667 1352"> <thead> <tr> <th colspan="2" data-bbox="207 772 667 877"><b>Table 1. Dosing and Administration for Adult Patients</b></th> </tr> <tr> <th data-bbox="207 877 423 989">Patient Population</th> <th data-bbox="423 877 667 989">Recommended Dosage Strength and Frequency</th> </tr> </thead> <tbody> <tr> <td data-bbox="207 989 423 1136">Adult rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis</td> <td data-bbox="423 989 667 1136">50 mg weekly</td> </tr> <tr> <td data-bbox="207 1136 423 1352" rowspan="2">Adult plaque psoriasis</td> <td data-bbox="423 1136 667 1247"><u>Starting Dose:</u> 50 mg twice weekly for 3 months</td> </tr> <tr> <td data-bbox="423 1247 667 1352"><u>Maintenance Dose:</u> 50 mg once weekly</td> </tr> </tbody> </table> <table border="1" data-bbox="207 1402 667 1829"> <thead> <tr> <th colspan="2" data-bbox="207 1402 667 1507"><b>Table 2. Dosing and Administration for Juvenile Idiopathic Arthritis</b></th> </tr> <tr> <th data-bbox="207 1507 423 1604">Pediatric Patients Weight</th> <th data-bbox="423 1507 667 1604">Recommended Dose</th> </tr> </thead> <tbody> <tr> <td data-bbox="207 1604 423 1688">63 kg (138 pounds) or more</td> <td data-bbox="423 1604 667 1688">50 mg weekly</td> </tr> <tr> <td data-bbox="207 1688 423 1829">Less than 63 kg (138 pounds)</td> <td data-bbox="423 1688 667 1829">0.8 mg/kg weekly</td> </tr> </tbody> </table>	<b>Table 1. Dosing and Administration for Adult Patients</b>		Patient Population	Recommended Dosage Strength and Frequency	Adult rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis	50 mg weekly	Adult plaque psoriasis	<u>Starting Dose:</u> 50 mg twice weekly for 3 months	<u>Maintenance Dose:</u> 50 mg once weekly	<b>Table 2. Dosing and Administration for Juvenile Idiopathic Arthritis</b>		Pediatric Patients Weight	Recommended Dose	63 kg (138 pounds) or more	50 mg weekly	Less than 63 kg (138 pounds)	0.8 mg/kg weekly	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘e’ and ‘a’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘E’ and ‘A’ may sound similar when spoken</li> </ul> <p><b>Overlapping Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (50 mg)</li> <li>- Dose and Frequency (50 mg once weekly)</li> <li>- Route of Administration (subcutaneous)</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘nbrel’ appear different when scripted and makes ‘Eperzan’ appear longer when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘nbrel’ sound different when spoken</li> </ul>
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Patient Population	Recommended Dosage Strength and Frequency																			
Adult rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis	50 mg weekly																			
Adult plaque psoriasis	<u>Starting Dose:</u> 50 mg twice weekly for 3 months																			
	<u>Maintenance Dose:</u> 50 mg once weekly																			
<b>Table 2. Dosing and Administration for Juvenile Idiopathic Arthritis</b>																				
Pediatric Patients Weight	Recommended Dose																			
63 kg (138 pounds) or more	50 mg weekly																			
Less than 63 kg (138 pounds)	0.8 mg/kg weekly																			

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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><b>Epiceram</b> (Disodium EDTA, glycerin, glyceryl stearate, PEG-100, petrolatum)</p> <ul style="list-style-type: none"> <li>- topical emulsion</li> <li>- use as directed</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Epe’ and ‘Epi’ may appear similar when scripted</li> <li>- ‘zan’ and ‘ram’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘Ep’</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘r’ and ‘ce’ appear different when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erzan’ and ‘iceram’ sound different when spoken</li> </ul> <p><b>- Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. single strength)</li> <li>- Dose (30 mg, 50 mg vs. apply amount)</li> <li>- Frequency of Administration (once weekly vs. use as directed)</li> </ul>
10.	<p><b>Epifrin</b> (epinephrine)</p> <ul style="list-style-type: none"> <li>- 0.5 %, 1 %, 2 % ophthalmic solution</li> <li>- no longer marketed/could not find product characteristics</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Epe’ and ‘Epi’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘Ep’</li> </ul>	<p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erzan’ and ‘ifrin’ sound different when spoken</li> </ul> <p><b>- Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 0.5 %, 1 %, 2 %)</li> <li>- Dose (30 mg, 50 mg vs. 1 drop)</li> <li>- Frequency of Administration (once weekly vs. use as directed)</li> </ul>

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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><b>Epipen (epinephrine)</b></p> <ul style="list-style-type: none"> <li>- 0.3 mg per syringe</li> <li>- use as directed for intramuscular injection</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Epe’ and ‘Epi’ may appear similar when scripted</li> <li>- ‘zan’ and ‘pen’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘Ep’</li> </ul>	<p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘erzan’ and ‘ipen’ sound different when spoken</li> </ul> <p><b>- ‘Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 0.3 mg)</li> <li>- Dose (30 mg, 50 mg vs. 1 syringe)</li> </ul>
12.	<p><b>Epogen (epoetin alfa)</b></p> <ul style="list-style-type: none"> <li>- single dose: 2,000 units, 3,000 units, 4,000 units, 10,000 units, 40,000 units per ml</li> <li>- multi-dose: 20,000 units/2 mL and 20,000 units /1 mL</li> </ul> <p>CKD: 50 units to 100 units per kg 3 times weekly (Pediatrics 50 units/kg 3 times weekly)</p> <p>Zidovudine-treated HIV patients: 100 units/kg 3 times weekly</p> <p>Chemotherapy patients:</p> <ul style="list-style-type: none"> <li>- Adults: 150 units/kg subcutaneously 3 times weekly or 40,000 units weekly</li> <li>- Pediatric (5 to 18 years): 600 units/kg intravenously weekly</li> </ul> <p>Surgery patients: 300 units/kg per day subcutaneously for 15 days total or 600 units/kg on 21, 14, and 7 days before surgery and on the day of surgery</p>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Eperzan’ and ‘Epogen’ may appear similar when scripted due to the similarity of length and shape</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Epe’ and ‘Epo’ may sound similar when spoken</li> </ul> <p><b>Overlapping Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of Administration (subcutaneous injection)</li> </ul>	<p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘rzan’ and ‘gen’ sound different when spoken</li> </ul> <p><b>- ‘Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 2,000 units, 3,000 units, 4,000 units, 10,000 units, 40,000 units per ml; 20,000 units/2 mL and 20,000 units /1 mL )</li> </ul>

No.	<p><b>Proposed name: Eperzan (Albiglutide)</b></p> <p><b>Dosage Form: powder for injection</b></p> <p><b>Strengths: 30 mg, 50 mg</b></p> <p><b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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><b>Mepergan (meperidine/promethazine)</b></p> <ul style="list-style-type: none"> <li>- 25 mg/25 mg per mL solution for intravenous or intramuscular injection</li> <li>- No longer marketed/could not find product characteristics</li> </ul>	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- ‘Eperzan’ and ‘epergan’ may appear similar when scripted</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both have the letter string ‘eper’</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- Mepergan starts with an M, which makes it appear different when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- The ‘M’ in ‘Mepergan’ makes it sound different from ‘eperzan’ when spoken</li> <li>- ‘z’ and ‘g’ sound different when spoken</li> </ul> <p><b>- Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (30 mg, 50 mg vs. 25 mg/25 mg per mL)</li> <li>- Route of Administration (subcutaneous vs. intravenous or intramuscular)</li> </ul>																																										
14.	<p><b>Efavirenz (Brand name Sustiva)</b></p> <ul style="list-style-type: none"> <li>- Capsules: 50 mg, 200 mg oral</li> <li>- Tablet: 600 mg oral</li> <li>- (b) (4)</li> <li>- Adult 600 mg once daily</li> <li>- With voriconazole: 300 mg</li> <li>- With rifampin: 800 mg once daily</li> </ul> <p><b>Pediatric Patients at Least 3 Years and at Least 10 kg</b></p> <table border="1" data-bbox="207 1619 618 1885"> <thead> <tr> <th>kg</th> <th>lbs</th> <th>dose</th> <th>kg</th> <th>lbs</th> <th>dose</th> </tr> </thead> <tbody> <tr> <td>10</td> <td>22</td> <td>200</td> <td>25</td> <td>55</td> <td>350</td> </tr> <tr> <td>&lt;15</td> <td>&lt;33</td> <td>mg</td> <td>&lt;32.5</td> <td>&lt;71.5</td> <td>mg</td> </tr> <tr> <td>15</td> <td>33</td> <td>250</td> <td>32.5</td> <td>71.5</td> <td>400</td> </tr> <tr> <td>&lt;20</td> <td>&lt;44</td> <td>mg</td> <td>&lt;40</td> <td>&lt;88</td> <td>mg</td> </tr> <tr> <td>20</td> <td>44</td> <td>300</td> <td>at least</td> <td>at least</td> <td>600</td> </tr> <tr> <td>&lt;25</td> <td>&lt;55</td> <td>mg</td> <td>40</td> <td>88</td> <td>mg</td> </tr> </tbody> </table>	kg	lbs	dose	kg	lbs	dose	10	22	200	25	55	350	<15	<33	mg	<32.5	<71.5	mg	15	33	250	32.5	71.5	400	<20	<44	mg	<40	<88	mg	20	44	300	at least	at least	600	<25	<55	mg	40	88	mg	<p><b>Orthographic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘E’</li> </ul> <p><b>Phonetic Similarities</b></p> <ul style="list-style-type: none"> <li>- Both start with ‘E’</li> </ul> <p><b>Overlapping Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (50 mg)</li> </ul>	<p><b>Orthographic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘favirenz’ appear different when scripted</li> </ul> <p><b>Phonetic Differences</b></p> <ul style="list-style-type: none"> <li>- ‘perzan’ and ‘favirenz’ sound different when spoken</li> </ul> <p><b>- Differing Product Characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of Administration (once weekly vs. once daily)</li> </ul>
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<b>No.</b>	<b>Proposed name: Eperzan (Albiglutide)</b> <b>Dosage Form: powder for injection</b> <b>Strengths: 30 mg, 50 mg</b> <b>Usual Dose: 30 mg subcutaneous inject once weekly, may increase to 50 mg</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> <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
15.	<b>Operand (povidine-iodine)</b> - 7.5 %, 10 % topical solution - antiseptic: apply to affected area as needed - surgical scrub: scrub for 5 minutes, rise - (b) (4)	<b>Orthographic Similarities</b> - ‘eper’ and ‘oper’ may appear similar when scripted <b>Phonetic Similarities</b> - ‘eper’ and ‘oper’ may sound similar when spoken	<b>Orthographic Differences</b> - ‘zan’ and ‘rand’ appear different when scripted <b>Phonetic Differences</b> - ‘zan’ and ‘rand’ sound different when spoken - <b>Differing Product Characteristics</b> - Strength (30 mg, 50 mg vs. 7.5 %, 10 %) - Dose (30 mg, 50 mg vs. apply amount) - Frequency of Administration (once weekly vs. as needed)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SARAH K VEE  
04/12/2013

LUBNA A MERCHANT on behalf of JAMIE C WILKINS PARKER  
04/12/2013

KELLIE A TAYLOR  
04/12/2013

CAROL A HOLQUIST  
04/12/2013