

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125504Orig1s000

PROPRIETARY NAME REVIEW(S)

Proprietary Name Memorandum

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review: March 19, 2014

Requesting Office or Division: Division of Dermatology and Dental Products (DDDP)

Application Type and Number: BLA 125504

Product Name and Strength: Cosentyx (Secukinumab) Powder for Injection, 150 mg
Cosentyx (Secukinumab) Injection, 150 mg/mL PFS
Cosentyx Sensoready Pen (Secukinumab) Injection,
150 mg/mL auto-injector

Product Type: Single ingredient product and Drug-device combination product

Rx or OTC: Rx

Applicant/Sponsor Name: Novartis

Submission Date: 02/12/2014

Panorama #: 2014-16911 and 2014-16912

DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh

DMEPA Associate Director: Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary names, Cosentyx and Cosentyx SensoReady Pen, were found acceptable in OSE review # 2013-784 and 2013-1313, dated September 12, 2013 under IND 100418.

We note that the dosage for the product changed from an initial review from [REDACTED] ^{(b) (4)} to “300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, and 3 followed by monthly maintenance dosing starting at week 4”. However, our initial review considered both the 150 mg and the 300 mg doses. Therefore, this memorandum is to communicate that DMEPA maintains the proposed proprietary names, Cosentyx and Cosentyx SensoReady Pen, are acceptable from both a promotional and safety perspective under the BLA 125504.

If you have further questions or need clarifications, please contact Teena Thomas, OSE project manager, at 301-796-0549.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Cosentyx and Cosentyx SensoReady Pen, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your February 12, 2014 submission are altered, the names must be resubmitted for review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CARLOS M MENA-GRILLASCA
03/20/2014

LUBNA A MERCHANT
03/20/2014

**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: September 12, 2013

Reviewer: Carlos M Mena-Grillasca, RPh, Safety Evaluator
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength(s): Cosentyx (Secukinumab) Powder for Injection, 150 mg
Cosentyx (Secukinumab) Injection, 150 mg/mL PFS
Cosentyx Sensoready Pen (Secukinumab) Injection,
150 mg/mL auto-injector

Application Type/Number: IND 100418

Applicant/Sponsor: Novartis

OSE RCM #: 2013-784
2013-1313

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name (b) (4) was found conditionally acceptable by DMEPA under RCM# 2012-992, dated September 20, 2012. However, the proposed name (b) (4) (b) (4) Therefore, the Sponsor decided to withdraw the name (b) (4) and submit the proposed name Cosentyx for review. In addition, the Sponsor is proposing the name Cosentyx Sensoready Pen for the single-use Auto Injector. We note that none of the product characteristics have changed since the review of the name (b) (4) in RCM# 2012-992.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 22, 2013, and May 31, 2013 proprietary name submissions, and June 7, 2013 amendment.

- Active Ingredient: Secukinumab
- Indication of Use: Treatment of adult patients with moderate to severe plaque-type psoriasis who are candidates for phototherapy or systemic therapy.
- Route of Administration: Subcutaneous Injection
- Dosage Form: Powder for Injection (vial); Solution for Injection (pre-filled syringe and auto-injector)
- Strength: 150 mg
- Dose and Frequency: (b) (4) (b) (4)
- How Supplied: 150 mg powder for injection in single-use vials
150 mg/mL injection in a single dose pre-filled syringe
150 mg/mL injection in a single dose autoinjector
- Storage: Store refrigerated at 2° - 8°C. Protect from direct exposure to light.
- Intended pronunciation: koe sen' tix
koe sen' tix sen soe re' dee

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 names are acceptable from a promotional perspective. DMEPA and the Division of Dermatology and Dental Products (DDDP) concurred with the findings of OPDP's promotional assessment of the proposed name. However, the medical officer team leader considered the modifier Sensoready to be promotional; therefore, DMEPA requested OPDP to reconsider their evaluation. OPDP re-evaluated the proposed name Cosentyx Sensoready Pen and maintained their original non-objection to the proposed name. DDDP finally deferred to OPDP's promotional evaluation of the proposed proprietary names.

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 August 15, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary names.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed names, Cosentyx and Cosentyx Sensoready Pen, have no intended meaning and are not derived from any other words.

The proposed name Cosentyx 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.

The proposed name Cosentyx Sensoready Pen is comprised of the root name, Cosentyx, and the modifiers, Sensoready Pen. The proposed modifiers, Sensoready Pen, refer to the name of the auto-injector device. The Sponsor did not provide data to support the proposed modifier is understood by health care practitioners and patients; however, the naming convention of adding a modifier to represent a specific device has been used before to differentiate the auto injector presentation from the vial and/or pre-filled syringe.

We note that modifiers may sometimes be omitted. If the modifier, Sensoready Pen, is omitted the pharmacist would have to call the prescriber to seek clarification or the patient may receive the pre-filled syringe or vial presentation. However, since Cosentyx is only available in a single strength the patient would still be receiving the correct product and dose. Furthermore, as with any product that is available in multiple dosage forms or packaging presentation the prescriber would need to indicate in the prescription the intended product.

Finally, we do not anticipate that the modifier 'Sensoready Pen' will be written on its own without the root name. Additionally, we did not identify any names that can be confused with 'Sensoready Pen' during our sound alike and look alike searches. Therefore, we do not find the modifier, Sensoready Pen, misleading or vulnerable to confusion and find it acceptable for this product.

2.2.3 FDA Name Simulation Studies

Cosentyx:

A total of 71 practitioners participated in DMEPA's prescription study for Cosentyx. The interpretations did not overlap with any currently marketed product; however, one participant in the voice study interpreted the name as "Proventix", which looks and sounds like the marketed product Proventil. Therefore, the name Proventil was included in our FMEA evaluation (section 2.2.5). Forty participants interpreted the name Cosentyx correctly: outpatient (n=21) and inpatient (n=19). Twenty participants misinterpreted the letter 'y' for 'i' and four participants misinterpreted the 'y' for 'e' in the voice study. Eighteen participants in the voice study misinterpreted the 's' for 'z'. Eight participants misinterpreted the 'x' for 's': outpatient (n=5), voice (n=3). We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

Cosentyx Sensoready Pen:

A total of 48 practitioners participated in DMEPA's prescription study for Cosentyx Sensoready Pen. The interpretations did not overlap with any currently marketed product nor did it appear to sound or look similar to any currently marketed products or products in the pipeline. Twenty-eight participants interpreted the name Cosentyx Sensoready Pen correctly: outpatient (n=15) and inpatient (n=13). Five participants omitted the modifiers Sensoready Pen: inpatient (n=2), voice (n=3). Thirteen participants misinterpreted the letter 'y' for 'i' and one participant misinterpreted the 'y' for 'e' in the voice study. One participants in the voice study misinterpreted the 'x' for 's'. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Stage of Review

In response to the OSE, May 5, 2013 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed name Cosentyx at the initial phase of the proprietary name review.

In response to the OSE, June 27, 2013 e-mail, the Division of Dermatology and Dental Products the DDDP expressed concern that the modifier Sensoready seemed promotional. However, OPDP maintained their non-objection to the proposed name, Cosentyx Sensoready Pen, and the review division deferred to OPDP's decision.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary names, Cosentyx and Cosentyx Sensoready Pen. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary names, Cosentyx and Cosentyx Sensoready Pen, identified by the primary reviewer, the Expert Panel Discussion (EPD), and prescription simulation studies.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and FDA Name Simulation Studies)

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Aosept	FDA	Cesamet	FDA	Cosopt	FDA
Apokyn	FDA	Chantix	FDA	Cosyntropin	FDA
Aventyl	FDA	Cogentin	FDA	Covaryx	FDA
Bosentan	FDA	Cognitex	FDA	Losartan	FDA
Cancidas	FDA	Cometriq	FDA	Lotronex	FDA
Casodex	FDA	Concerta	FDA	Lovenox	FDA
Cenestin	FDA	Condylox	FDA	Lusedra	FDA
Centrax	FDA	Cortrosyn	FDA	Sensorcaine	FDA
Ceralyte	FDA	Cosamin	FDA		
Cerebyx	FDA	Cosmegen	FDA		

Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Proventil	Rx Study				
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	FDA				

Our analysis of the 30 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the names will pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Dermatology and Dental Products via e-mail on August 21, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on August 22, 2013, they stated no additional concerns with the proposed proprietary names, Cosentyx and Cosentyx Sensoready Pen.

3 CONCLUSIONS

The proposed proprietary names are acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE SPONSOR

We have completed our review of the proposed proprietary names, Cosentyx and Cosentyx Sensoready Pen, and have concluded that these names are acceptable.

The proposed proprietary name must be re-reviewed upon submission of the BLA. The results are subject to change. If any of the proposed product characteristics as stated in your March 22, 2013, and May 31, 2013 proprietary name submissions and June 7, 2013 amendment are altered the names must be resubmitted for review.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

13. *Red Book* (www.thomsonhc.com/home/dispatch)

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

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

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

15. *Medical Abbreviations* (www.medilexicon.com)

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

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

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

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

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

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

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

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

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

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

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

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name Cosentyx Sensoready Pen	Scripted May Appear as	Spoken May Be Interpreted as
C	A, E, O, G, L, U	K
c	a, e, i, l, o	k
o	a, c, e, u, number 0	Any vowel
s	g, n, r, v	sh
e	a, i, l, o, u, p	Any vowel
n	m, u, x, r, h, s	m
t	r, l, f, x, A	D
y	f, p, u, v, x, Z, j, g	Any vowel
x	a, f, k, n, r, t, v, y	K, ck, s, c, t
S	G, L, Z, 5	X, c
r	e, n, s, v	--
a	el, ci, cl, d, o, u	Any vowel
d	cl, ci	b, t
P	F, D, O	B
p	Yn, ys, g, j, l, q, J, y, z	b
Letter Strings	Scripted May Appear as	Spoken May Be Interpreted as
ty	tij	--
en	ur, w	--
re	u	--
ea	r, w	--
Co	--	Pro

Appendix C: Prescription Simulation Samples and Results

Figure 1. Cosentyx Study (Conducted on April 5, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Cosentyx 150mg subcutaneous X1 dose</i></p>	<p>Cosentyx 150 mg Use as Directed Disp. #4</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Cosentyx 150mg qd x4</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 8/9/2013

193 People Received Study

71 People Responded

Study Name: Cosentyx

Total	24	24	23	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CONSENTYS	1	0	0	1
COSENTIX	0	4	0	4
COSENTRYX	0	0	1	1
COSENTYN	0	0	1	1
COSENTYS	4	0	0	4
COSENTYX	19	0	21	40
COVENTEX	0	1	0	1
COZENTEX	0	3	0	3
COZENTICS	0	3	0	3
COZENTIX	0	11	0	11
PROVENTIX	0	1	0	1
PROZENTIX	0	1	0	1

Figure 2. Cosentyx Sensoready Pen Study (Conducted on July 3, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>Cosentyx Sensoready Pen 150mg</i> <i>subq once</i></p>	<p>Cosentyx Sensoready Pen Use as Directed Disp. #4</p>
<p><u>Outpatient Prescription:</u> <i>Cosentyx Sensoready Pen</i> <i>WAD</i> <i>#4</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 8/9/2013

191 People Received Study

48 People Responded

Study Name: Cosentyx Sensoready Pen

Total	16	14	18	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CLOSENTIX SENSOR READY PEN	0	1	0	1
COCENTIX	0	1	0	1
COCENTRIX SENSORREADY PEN	0	1	0	1
CONSENSOREADY PEN	1	0	0	1
CONSENTIX SENA READIPEN	0	1	0	1
CONSENTYX SENSOREADY PEN	0	0	1	1
COSENTEX TESTAPEN	0	1	0	1
COSENTICS SENSOREADY PEN	0	1	0	1
COSENTIX	0	2	0	2
COSENTIX SENOREDIPEN	0	1	0	1
COSENTIX SENSOR READY PEN	0	4	0	4
COSENTIX SENSOR REDI PEN	0	1	0	1
COSENTYX	0	0	2	2
COSENTYX SENSEREADY PEN	0	0	1	1
COSENTYX SENSOREADY PEN	15	0	13	28
COSENTYX SENSOVEUDG PEN	0	0	1	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Cosentyx	Failure preventions
1.	Aosept	n/a	Look	Name lack significant orthographic similarities.
2.	CeraLyte	n/a	Look	Family name for a product line of over the counter products (i.e. CeraLyte potassium free, CeraLyte 50, CeraLyte 70, CeraLyte 90). A prescription would need to include specific information to identify the product.
3.	Cesamet	Nabilone	Look	Name lack significant orthographic similarities.
4.	Cognitex	n/a	Look	Family name for a product line of over the counter products (i.e. Cognitex Basics and Cognitex with Pregnenolone & NeuroProtection Complex). A prescription would need to include specific information to identify the product.
5.	Cosamin DS	Glucosamine Hydrochloride and Chondroitin	Look	Name lack significant orthographic similarities.
6.	(b) (4) ***	Secukinumab	Look	Proposed proprietary name for this IND. Withdrawn by the applicant on March 22, 2013.
7.	Cosmegen	Dactinomycin	Look	Name lack significant orthographic similarities.
8.	Cosopt	Dorzolamide hydrochloride and Timolol maleate	Look	Name lack significant orthographic similarities.
9.	n/a	Cosyntropin	Look	Name lack significant orthographic similarities.
10.	Lotronex	Alosetron hydrochloride	Look	Name lack significant orthographic similarities.
11.	Lovenox	Enoxaparin sodium	Look	Name lack significant orthographic similarities.

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>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
12.	<p>Apokyn (Apomorphine Hydrochloride) Injection 30 mg/3 mL cartridges</p> <p><u>Dosage:</u> The dose must be titrated on the basis of effectiveness and tolerance, starting at 0.2 mL (2 mg) and up to a maximum recommended dose of 0.6 mL (6 mg). For patients with mild and moderate renal impairment, the testing dose and subsequently the starting dose should be reduced to 0.1 mL (1 mg). The prescribed dose is used on an as needed basis to treat existing “off” episodes.</p>	<p><u>Orthographic:</u> The capital letter ‘C’ may look like the capital letter ‘A’. Both names have an upstroke in a similar position (‘t’ vs. ‘k’) and share the letters ‘o’, ‘n’ and ‘y’ in similar positions.</p> <p><u>Dosage form and Strength:</u> Both products are injections available in a single strength.</p> <p><u>Route of administration:</u> Both products are administered subcutaneously.</p>	<p><u>Orthographic:</u> Cosentyx has 8 letters vs. Apokyn has 6 letters and look shorter when scripted. Apokyn has a downstroke letter in the second position that is not present in Cosentyx, giving the names a different shape when scripted.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. as needed to treat “off” episodes.</p>
13.	<p>Aventyl (Nortriptyline Hydrochloride) Capsules: 10 mg and 25 mg Oral Solution: 10 mg/5 mL</p> <p><u>Dosage:</u> 25 mg three or four times daily or the total daily dose may be given once daily. Doses above 150 mg per day are not recommended.</p> <p><i>Note: Aventyl capsules are discontinued. However, generic capsules are available in 10 mg, 25 mg, 50 mg, and 75 mg.</i></p>	<p><u>Orthographic:</u> Both names have similar number of letters (8 vs. 7). The capital letter ‘C’ may look like the capital letter ‘A’. Both names share the same letter string ‘enty’ in the same position.</p> <p><u>Dose:</u> Both products may overlap in dose (150 mg)</p>	<p><u>Orthographic:</u> The letter string ‘os’ that follows the capital letter ‘C’ in Cosentyx looks different than the letter ‘v’ that follows the capital letter ‘A’ in Aventyl. In addition, Aventyl ends in an upstroke letter ‘l’ that is not present in Cosentyx, which may differentiate the names when scripted.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once, three or four times daily</p> <p><u>Dosage form:</u> Injection vs. capsules or oral solution. Since Aventyl is available in more than one dosage form the prescriber would need to specify the dosage form on a prescription.</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
14.	<p>Tracleer (Bosentan) Tablets 62.5 mg and 125 mg</p> <p><u>Dosage:</u> 62.5 mg twice daily for 4 weeks, and then increase to 125 mg twice daily</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters and share the letters 'os' and 'nt' in the same positions in the name. The letter last letter 'n' in Bosentan may look like the last letter 'x' in Cosentyx.</p>	<p><u>Orthographic:</u></p> <p>The initial letter 'B' in Bosentan looks different than the initial letter 'C' in Cosentyx. Cosentyx has a downstroke letter 'y' that is not present in Bosentan, which may differentiate the names when scripted.</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Bosentan is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. twice daily</p>
15.	<p>Cancidas (Caspofungin Acetate) for Injection 50 mg and 70 mg vials</p> <p><u>Dosage:</u></p> <p><i>Adults</i> 50 - 70 mg by intravenous infusion over 1 hour once daily for 7 to 14 days (treatment should continue for at least 7 days after both neutropenia and clinical symptoms are resolved).</p> <p><i>Pediatric (3 mos. to 17 years)</i> 50 – 70 mg/m² by intravenous infusion over 1 hour once daily (same duration of treatment as adults)</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters. Both names begin with the capital letter 'C' and have an upstroke in the same position ('t' vs. 'd'). Both names share the letters 's', and 'n'. The letter string 'ose' may look like the letter string 'anc' when scripted.</p> <p><u>Dosage form:</u></p> <p>Both products are available as lyophilized powder for injection in single-use vials</p>	<p><u>Orthographic:</u></p> <p>Cosentyx has a downstroke letter 'y' that is not present in Cancidas, which may differentiate the names when scripted.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily for 7 to 14 days (or until neutropenia and clinical symptoms resolve).</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Cancidas is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
16.	<p>Casodex (Bicalutamide) Tablets, 50 mg</p> <p><u>Dosage:</u> 50 mg once daily</p>	<p><u>Orthographic:</u> Both names have similar number of letters (8 vs. 7), begin with the capital letter 'C', and share the letter 's' and 'x' in similar positions. Both names have an upstroke ('t' vs. 'd') in a similar position.</p> <p><u>Strength:</u> Both products are available in a single strength.</p>	<p><u>Orthographic:</u> Cosentyx has a downstroke letter 'y' that is not present in Casodex, which may differentiate the names when scripted.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily</p>
17.	<p>Cenestin (Synthetic conjugated estrogens, A) Tablets</p> <p>0.3 mg, 0.45 mg, 0.625 mg, 0.9 mg, 1.25 mg</p> <p><u>Dosage:</u> 0.3 mg to 1.25 mg orally once daily</p>	<p><u>Orthographic:</u> Both names have the same number of letters. Both names begin with the capital letter 'C', share the upstroke letter 't' and the letter 'e' in the same positions. In addition, the names share the letter 's' and 'n'. The letter last letter 'n' in Cenestin may look like the last letter 'x' in Cosentyx.</p>	<p><u>Orthographic:</u> Cosentyx has a downstroke letter 'y' that is not present in Cenestin, which may differentiate the names when scripted.</p> <p><u>Strength:</u> Cosentyx is a single strength product vs. Cenestin is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
18.	<p>Centrax (Prazepam)</p> <p>Capsules: 5 mg, 10 mg, 20 mg</p> <p>Tablets: 10 mg</p> <p><u>Dosage:</u> 10 – 60 mg orally per day administered 2 – 3 times per day.</p> <p><i>Note: Discontinued product with no therapeutic or generic equivalent available.</i></p>	<p><u>Orthographic:</u></p> <p>Both names have similar number of letters (8 vs. 7), begin with the capital letter ‘C’, share the letter string ‘ent’ and the ending letter ‘x’.</p>	<p><u>Orthographic:</u></p> <p>Cosentyx has 4 letters between the capital letter and the upstroke vs. 2 letters in Centrax. In addition, Cosentyx has a downstroke letter ‘y’ that is not present in Cenestin, giving the names a different shape when scripted.</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Centrax is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. 2 – 3 times per day</p>
19.	<p>Cerebyx (Fosphenytoin Sodium) Injection</p> <p>100 mg PE/2 mL 500 mg PE/10 mL</p> <p><u>Dosage:</u> 10 to 20 mg PE/kg by intravenous infusion at 100 to 150 mg PE/min or by intramuscular injection.</p> <p>The initial maintenance dose is 4 to 6 PE/kg/day.</p>	<p><u>Orthographic:</u></p> <p>Both names have a similar number of letters (8 vs. 7), begin with the capital letter ‘C’, have an upstroke letter in a similar position (‘t’ vs. ‘b’), and share the letters ‘e’, ‘yx’ in the same position.</p> <p><u>Dosage form:</u></p> <p>Both products are injections.</p> <p><u>Dose:</u></p> <p>Both products may overlap in dose (150 mg or 300 mg)</p>	<p><u>Orthographic:</u></p> <p>Cosentyx contains an additional letter ‘n’ before the upstroke which may help differentiate the names when scripted.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily or more frequently if required</p> <p><u>Other:</u></p> <p>Cerebyx is used in a hospital setting and requires dilution in 5% dextrose or 0.9% saline solution to a concentration ranging from 1.5 to 25 mg PE/mL. In addition, due to the risk of hypotension, continuous monitoring of the electrocardiogram, blood pressure, and respiratory function is essential and the patient should be observed throughout the period where maximal serum pheytoin concentrations occur, approximately 10 to 20 minutes after the end of fosphenytoin sodium injection infusion.</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
20.	<p>Chantix (Varenicline Tartrate) Tablets 0.5 mg, 1 mg</p> <p><u>Dosage:</u> Starting week: 0.5 mg orally once daily on day 1-3 and 0.5 mg orally twice daily on days 4-7.</p> <p>Continuing weeks: 1 mg orally twice daily for a total of 12 weeks</p>	<p><u>Orthographic:</u> Both names have a similar number of letters (8 vs. 7), begin with the capital letter 'C', share the letter string 'nt' and the final letter 'x'.</p>	<p><u>Orthographic:</u> Chantix has an additional upstroke letter 'h' which is not present in Cosentyx. In addition, Cosentyx has a downstroke letter 'y' which is not present in Chantix. These orthographic differences give the names a different shape when scripted. Finally, the letters 'os' in Cosentyx in the corresponding position where the upstroke letter 'h' appears in Chantix further differentiate the names.</p> <p><u>Strength:</u> Cosentyx is a single strength product vs. Chantix is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once or twice daily</p>
21.	<p>Cogentin (Benztropine Mesylate) Tablets: 0.5 mg, 1 mg, 2 mg Injection, 2 mg/2 mL</p> <p><u>Dosage:</u> 0.5 mg to 6 mg (orally, intramuscularly, or intravenously) at bedtime or divided doses (2-4 times a day)</p> <p><i>Note: Cogentin tablets are discontinued but generic equivalents are available.</i></p>	<p><u>Orthographic:</u> Both names have the same number of letters, begin with the letter string 'Co' and share the letter string 'ent'. In addition, both names share a down stroke letter ('g' vs. 'y').</p> <p><u>Dosage form:</u> Both products are available as injections.</p>	<p><u>Orthographic:</u> Although both names have an down stroke letter, the position of the 'g' at the beginning of Cogentin vs. the 'y' at the end of the Cosentyx give the names a different shape when scripted.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily or divided daily doses</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
22.	<p>Cometriq (Cabozanitib) Capsules</p> <p>20 mg and 80 mg</p> <p>Product available in bottles of 20 mg capsules and cartons.</p> <p>140 mg daily-dose carton contains seven 80 mg and twenty-one 20 mg capsules</p> <p>100 mg daily-dose carton contains seven 80 mg and seven 20 mg capsules</p> <p>60 mg daily-dose carton contains twenty-one 20 mg capsules</p> <p><u>Dosage:</u></p> <p>140 mg orally daily (one 80 mg and three 20 mg capsules) without food.</p> <p>100 mg and 60 mg daily doses are required for dose adjustment due to adverse reactions.</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters, start with the letter string ‘Co’ and share the same upstroke letter ‘t’. Both names have a down stroke (‘y’ vs. ‘q’) in similar positions.</p>	<p><u>Orthographic:</u></p> <p>The middle portions of the names (‘san’ vs. ‘me’) look different when scripted. The down stroke letters in the names (‘y’ vs. ‘q’) are in different positions and give the names a different shape when scripted.</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Cometriq is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily</p>
23.	<p>Concerta (Methylphenidate Hydrochloride) Extended-release Tablets</p> <p>18 mg, 27 mg, 36 mg, and 54 mg</p> <p><u>Dosage:</u></p> <p>18 mg to 72 mg orally once daily in the morning</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters, begin with the letter string ‘Co’ and share the letters ‘n’, ‘e’, and ‘t’ in similar positions.</p>	<p><u>Orthographic:</u></p> <p>Cosentyx has a down stroke letter ‘y’ that is not present in Concerta, which gives the names a different shape when scripted.</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Concerta is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
24.	<p>Condylox (Podofilox)</p> <p>Gel, 0.5% Topical Solution, 0.5%</p> <p><u>Dosage:</u> Apply twice daily morning and evening (every 12 hours), for 3 consecutive days, then withhold use for 4 consecutive days. This one week cycle of treatment may be repeated up to four times until there is no visible wart tissue.</p>	<p><u>Orthographic:</u> Both names have the same number of letters, begin with the letter string 'Co', share the letters 'n', 'y', and 'x' in similar positions, and both have an up stroke letter ('t' vs. 'd').</p> <p><u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.</p>	<p><u>Orthographic:</u> Condylox has an additional upstroke letter 'l' following the share downstroke 'y', giving the names a different shape when scripted. Finally, the additional letter 'o' in Condylox separates the shared letters 'y' and 'x' and make the names look different.</p> <p><u>Dosage forms:</u> Condylox is available in two dosage forms (topical solution and gel); therefore, a prescriber should include the dosage form on the prescription to differentiate between the products.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. twice daily for 3 consecutive days, withhold use for 4 consecutive days and repeat up to 4 cycles</p>
25.	<p>Cortrosyn (Cosyntropin) for Injection</p> <p>0.25 mg</p> <p><u>Dosage:</u> 0.125 to 0.75 mg intramuscularly or intravenously or as an intravenous infusion over a 4 to 8 hour period</p>	<p><u>Orthographic:</u> Both names have a similar number of letters (8 vs. 9), begin with the letter string 'Co', and share the letters 's', 'n', 't' and 'y'.</p> <p><u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.</p> <p><u>Dosage form:</u> Both products are injections.</p>	<p><u>Orthographic:</u> Although the names share 4 letters ('n', 's', 't', and 'y'), they are located in different positions in each name giving them a different shape when scripted. There are two letters separating the shared letter string 'Co' from the upstroke letter 't' in Cortrosyn vs. four letter separating the same shared letters in Cosentyx. Likewise, there are 3 letters separating the shared upstroke letter 't' from the downstroke letter 'y' in Cortrosyn vs. no letters separating the same shared letters in Cosentyx. These differences gives each name a different shape when scripted.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. one time use as a screening agent</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
26.	<p>Covaryx (Estrogens, Esterified and Methyltestosterone) Tablets</p> <p>1.25 mg/2.5 mg</p> <p><u>Dosage:</u> 1 capsule daily</p>	<p><u>Orthographic:</u></p> <p>Both names have a similar number of letters (8 vs. 7), begin with the letter string 'Co', and end with the letter string 'yx'</p> <p><u>Strength:</u></p> <p>Both are single strength products and thus no strength is required on a prescription.</p>	<p><u>Orthographic:</u></p> <p>Cosentyx has an upstroke letter 't' that is not present in Covaryx, which gives the names a different shape when scripted.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once daily</p> <p><u>Dose:</u></p> <p>150 mg or 300 mg vs. 1 capsule</p>
27.	<p>Losartan Potassium Tablets, 25 mg, 50 mg, 100 mg</p> <p><u>Dosage:</u> 25 to 100 mg once or twice daily. Maximum daily dose is 100 mg.</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters. The capital letter 'L' may look like the capital letter 'C' when scripted. Both names share the letter string 'os' and the upstroke letter 't' in the same position. Both names share the letter 'n'.</p>	<p><u>Orthographic:</u></p> <p>Cosentyx has a down stroke letter 'y' that is not present in Losartan, which gives the names a different shape when scripted.</p> <p><u>Strength:</u></p> <p>Cosentyx is a single strength product vs. Losartan is available in multiple strengths, which would be required on a prescription. In addition, there is no overlap in strength or dose.</p> <p><u>Frequency of administration:</u></p> <p>Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. once or twice daily</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
28.	<p>Lusedra (Fospropofol Disodium) Injection 1,050 mg/30 mL</p> <p><u>Dosage:</u> <u>Standard dosing regimen:</u> initial intravenous bolus dose of 6.5 mg/kg followed by supplemental doses of 1.6 mg/kg as needed. No initial dose should exceed 16.5 mL; no supplemental dose should exceed 4 mL</p> <p><u>Modified dosing regimen</u> [for patients who are ≥65 years of age or who have severe systemic disease (ASA P3 or P4)]: 75% of the standard dosing regimen</p> <p><i>Note: Discontinued product with no generic equivalent available.</i></p>	<p><u>Orthographic:</u> Both names have a similar number of letters (8 vs. 7). The capital letter ‘C’ may look like the capital letter ‘L’ when scripted. Both names share the letter string ‘se’ and an upstroke (‘t’ vs. ‘d’) in similar positions.</p> <p><u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.</p> <p><u>Dosage form:</u> Both products are injections.</p>	<p><u>Orthographic:</u> Cosentyx has a down stroke letter ‘y’ that is not present in Lusedra, which gives the names a different shape when scripted.</p> <p><u>Setting of use:</u> Lusedra is indicated for monitored anesthesia care and requires the use of supplemental oxygen and continuous monitoring with pulse oximetry, electrocardiogram, and frequent blood pressure measurements.</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. one time during procedure</p>
29.	<p>Proventil HFA (Albuterol Sulfate) Aerosol, 200 Inhalations</p> <p><u>Dosage:</u> 1-2 inhalations every 4 to 6 hours OR 2 inhalations 15 to 30 minutes before exercise</p>	<p><u>Phonetic:</u> Both names have 3 syllables. First syllable: ‘Pro’ vs. ‘Co’ have same ending sound ‘o’. Second syllable: ‘ven’ vs. ‘sen’ have same ending sound ‘en’. Third syllable: ‘til’ vs. ‘tix’ have same beginning sound ‘ti’.</p> <p><u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.</p>	<p><u>Phonetic:</u> Although each one of the three syllables have a portion with an overlapping sound, they also have a portion that sound different. First syllable: ‘Pro’ vs. ‘Co’ have different beginning sound (‘P’ is a plosive bilabial sound vs. ‘C’ is a plosive velar sound) Second syllable: ‘ven’ vs. ‘san’ have different beginning sound (‘v’ is a fricative labio-dental sound vs. ‘s’ is a fricative alveolar sound) Third syllable: ‘l’ vs. ‘x’ have different ending sound (‘l’ is lateral alveolar sound vs. ‘x’ is affricate velar sound)</p> <p><u>Frequency of administration:</u> Once on week 0, 1, 2, 3, 4 followed by once every 4 weeks vs. every 4 to 6 hours or 15 to 30 minutes before exercise.</p>

No.	<p>Proposed names: Cosentyx Cosentyx Sensoready Pen</p> <p>Dosage Form(s): -Single-use vials for injection -Pre-filled Syringes Injection -Autoinjector</p> <p>Strength: 150 mg</p> <p>Usual Dose: _____ (b) (4) _____ (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
30.	<p>Sensorcaine (Bupivacaine) Injection, 0.25% and 0.5%</p> <p>Sensorcaine (Bupivacaine HCl with Epinephrine) Injection, 0.25% and 0.5%</p> <p><u>Dosage:</u></p> <p>Individualized. Dose varies with the anesthetic procedure, the area to be anesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, the depth of anesthesia and degree of muscle relaxation required, the duration of anesthesia desired, individual tolerance, and the physical condition of the patient.</p> <p>Most experience to date is with single doses of up to 225 mg with epinephrine 1:200,000 and 175 mg without epinephrine. The doses may be repeated up to once every three hours.</p>	<p><u>Orthographic:</u></p> <p>The name Sensorcaine is similar to the modifier Sensoready. Both share the beginning portion of the name ‘Sensor’ and the letter string ‘ca’ in Sensorcaine may look like the letter string ‘ra’.</p> <p><u>Dosage form and dose:</u></p> <p>Both products are injections and they overlap in the 150 mg dose.</p>	<p><u>Orthographic:</u></p> <p>Sensoready has an upstroke letter ‘d’ and a down stroke letter ‘y’ at the end of the name that gives it a different shape when scripted.</p> <p><u>Setting of use:</u></p> <p>Sensorcaine is used in a doctor’s office, clinic or hospital.. The product is likely to be stocked and not dispensed to an individual patient.</p> <p><u>Other:</u></p> <p>We do not anticipate that the modifier ‘Sensoready’ or ‘Sensoready Pen’ will be written on its own without the root name.</p>

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/s/

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09/12/2013

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