

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**125261**

**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**

**Date:** August 28, 2009

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Division of Medication Error Prevention and Analysis (DMEPA)

**Subject:** Proprietary Name Review

**Drug Name:** Stelara (Ustekinumab) Injection  
45 mg/0.5 mL and 90 mg/mL vials

**Application Type/Number:** BLA 125261

**Applicant:** Centocor Ortho Biotech, Inc.

**OSE RCM #:** 2009-1372

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## **EXECUTIVE SUMMARY**

This re-assessment of the proprietary name is written in response to a notification that BLA 125261 will be approved within 90 days. DMEPA found the proposed proprietary name, Stelara, acceptable in OSE Review #2008-812, dated December 8, 2008.

During this re-review we identified eleven new names for their similarity to Stelara. The results of the Failure Mode Effects Analysis found that the proposed name, Stelara, is not vulnerable to name confusion that could lead to medication errors with any of the 11 names. Thus, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Stelara, for this product.

DMEPA considers this a final review, however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Dermatology and Dental Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

## **1 BACKGROUND**

### **1.1 REGULATORY HISTORY**

In our initial review of the proposed name Stelara (OSE Review 2007-1407), DMEPA objected to the name because of orthographic similarity to Stalevo. In our most recent review of the name (OSE Review 2008-812, dated December 8, 2008), we reversed our decision and found the name acceptable because the Applicant had proposed to restrict distribution of Stelara to a limited number of specialty pharmacy providers.

### **1.2 PRODUCT INFORMATION**

Stelara is the proposed proprietary name for Ustekinumab Injection. Stelara is indicated for the treatment of adult patients (18 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Stelara is administered subcutaneously and the recommended dose is as follows:

- For patients weighing  $\leq 100$  kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients weighing  $> 100$  kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

Stelara is intended for subcutaneous administration by a healthcare provider. It will be available in 40 mg/0.5 mL and 90 mg per 1 mL single use vials. Stelara should be stored upright and refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Keep the product in the original carton to protect from light until the time of use. Do not shake. Stelara has been approved in Canada and Europe within the last 8 months.

The Applicant will restrict Stelara distribution to authorized wholesalers and specialty distributors and will not sell Stelara directly to any other customers (e.g., retail pharmacy, hospital). Wholesalers and specialty distributors are free to sell Stelara to their customers based upon demand.

## **2 METHODS AND MATERIALS**

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a re-assessment of a proprietary name 90 days prior to approval of an application. Section 2.1 identifies the specific search criteria associated with the proposed proprietary name, Stelara.

## 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'S' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>1,2</sup>

To identify drug names that may look similar to Stelara, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (3, capital letter 'S', lower case 't' and 'l'), downstrokes (none), cross strokes (one, lower case 't'), and dotted letters (none). Additionally, several letters in Stelara may be vulnerable to ambiguity when scripted, including the capital letter 'S' which may appear as capital letters 'D' or 'G'; lower case 't' may look like lower case 'f', 'l', or 'x'; lower case 'e' may look like lower case 'a', undotted 'i', 'l' or 'o'; lower case letter 'l' may appear as lower case 'e', undotted 'i', or uncrossed 't'; lower case 'a' may appear as lower case 'ce', 'ci', 'e', 'o', or 'u'; and lower case 'r' may appear as lower case 'n', 's', or 'v'. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Stelara.

When searching to identify potential names that may sound similar to Stelara, the DMEPA staff search for names with similar number of syllables (three), stresses (STE-la-ra, ste-LA-ra, or ste-la-RA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as, 'Ste' may sound like 'Sti'. The Applicant did not provide their intended pronunciation of the proprietary name in the proposed name submission and, therefore, it could not be taken into consideration. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 3 RESULTS

### 3.1 DATABASE AND INFORMATION SOURCES

The searches of the databases listed in Section 6 yielded a total of 17 names as having some similarity to the name Stelara.

Twelve of the names were thought to look like Stelara. These include ~~\_\_\_\_\_~~ Stalevo, Stelazine, Statuss, Starlix, Fludara, Aldara, Skelaxin, ~~\_\_\_\_\_~~. Two of the names were thought to sound like Stelara. These include Alera and Strentarga. The remaining 3 names, Strattera, ~~\_\_\_\_\_~~ and Stellaria were thought to look and sound similar to Stelara.

b(4)

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 16, 2009.

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

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

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### 3.2 EXPERT PANEL DISCUSSION

The Expert Panel, as described in Appendix A, section 2, reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Stelara.

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

### 3.3 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in two additional names, Relera and \_\_\_\_\_, which were thought to look and/or sound similar to Stelara and represent a potential source of drug name confusion. b(4)

Six names (see Appendix B) were identified that were also in our initial Stelara proprietary name review (OSE Review 2007-1407, dated March 7, 2008). None of Stelara's product characteristics have changed since that review. Therefore, the original assessment is maintained. Please see OSE Review 2007-1407 for a detailed analysis of those names.

Thirteen names were evaluated for their potential similarity to the proposed name, Stelara. One name lacked orthographic and/or phonetic similarity and was not evaluated further (see Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with the remaining 12 names and lead to medication errors. This analysis determined that the name similarity between Stelara was unlikely to result in medication errors with 11 of the 12 products for the reasons presented in Appendices D through G. The remaining product, Stalevo, has orthographic similarities to Stelara and is discussed in Section 4 below.

## 4 DISCUSSION

Although DMEPA was concerned with the orthographic similarities between Stelara and Stalevo during our previous review, the Applicant proposed restricted distribution of Stelara which alleviated our concerns; thus, we found the name Stelara acceptable in OSE Review 2008-812. Subsequently, the decision has been made that Stelara will not have a restricted method of pharmacy distribution. The product will be distributed via normal pharmacy channels. Therefore, we re-evaluated the orthographic similarities between Stelara and Stalevo.

Our evaluation determined that despite the change in the method of product distribution, Stelara and Stalevo have no overlapping product characteristics (see Appendix H) and this will minimize the potential for name confusion resulting in medication errors. Additionally, Stelara is only to be administered to patients by a healthcare provider and it is likely this will take place in a physician's office or a clinic. In contrast, Stalevo can be self-administered by patients and or caretakers. Thus, DMEPA has no objections to the proposed name, Stelara, despite distribution of the product through regular pharmacy channels.

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## **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Stelara, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Stelara, for this product at this time, even though the product will now be distributed through normal pharmacy channels.

DMEPA considers this a final review, however, if approval of the BLA is delayed beyond 90 days from the date of this review, the Division of Dermatology and Dental Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

### **5.1 COMMENTS TO THE DIVISION**

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarification, please contact Janet Anderson, OSE Project Manager, at 301-796-0675.

## 6 REFERENCES

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

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

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

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

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

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

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in review divisions.

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

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

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

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

7. ***Electronic online version of the FDA Orange Book*** (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))

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

10. **Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://www.thomson-thomson.com))**

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

11. **Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://www.naturaldatabase.com))**

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

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

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolph's Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. **USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)**

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

16. **Medical Abbreviations Book**

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

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>3</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases

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

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

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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

<sup>5</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

**Table 1.** Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

| Type of similarity | Considerations when searching the databases |   |   |
|--------------------|---|---|---|
|                    | Potential causes of drug name similarity    | Attributes examined to identify similar drug names  | Potential Effects   |
| Look-alike         | Similar spelling                            | Identical prefix<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics  | <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<br>Length of the name<br>Upstrokes<br>Down strokes<br>Cross-strokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>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<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | <ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>   |

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

### 1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the

proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

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

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

## **3. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

***“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”***

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

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

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<sup>6</sup> 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.

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

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

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

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

**Appendix B: Names previously reviewed and determined not to pose a safety risk.**

| Name      | Name                            |
|-----------|---------------------------------|
| Stelazine | <del>                    </del> |
| Fludara   | Strattera                       |
| Aldara    | Stellaria                       |

b(4)

**Appendix C: Names Lacking Orthographic and/or Phonetic Similarity.**

| Name       | Similarity to Stelara |
|------------|-----------------------|
| Strentarga | Sound                 |

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

**Appendix D: Drug products that are discontinued**

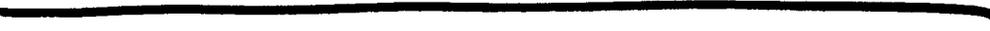
| Proprietary Name   | Similarity to Stelara | Status and Date  |
|--|-----------------------|--|
| <p>Status (Family Tradename)<br/> <u>Status</u><br/>                     (Phenylpropanolamine<br/>                     12.5 mg/Codeine Phosphate<br/>                     10 mg/Guaifenesin 200 mg)<br/>                     per 5 mL Oral Liquid</p> <p><u>Status DM</u><br/>                     (Chlorpheniramine Maleate<br/>                     2 mg/Dextromethorphan<br/>                     Hydrobromide 15 mg/<br/>                     Phenylephrine<br/>                     Hydrochloride 10 mg) per<br/>                     5 mL Syrup</p> <p><u>Status Green</u><br/>                     (Chlorpheniramine Maleate<br/>                     2 mg/Hydrocodone Bitartrate<br/>                     2.5 mg/Phenylephrine<br/>                     Hydrochloride 5 mg/<br/>                     Pseudoephedrine<br/>                     Hydrochloride 3.3 mg/<br/>                     Prilamine Maleate 3.3 mg)<br/>                     per 5 mL Syrup</p> | <p>Look</p>           | <p>Status was discontinued in 2000 and there are no generics available. Unable to determine the date of discontinuation of Status DM and Status Green or to definitively determine whether or not equivalent products are available.</p> |

**Appendix E: Names within the Agency**

| Name   | Similarity to Stelara | Comments |
|--|-----------------------|----------|
|  |                       |          |

b(4)

**Appendix F: Products with no numerical overlap in strength, dose and route of administration**

| Product name with potential for confusion   | Similarity to Stelara | Strength                        | Usual Dose  |
|---|-----------------------|---------------------------------|---|
| Stelara   | NA                    | 45 mg/0.5 mL and 90 mg per 1 mL | 45 mg (weight $\leq$ 100 kg) or 90 mg (weight $>$ 100 kg) subcutaneously once and 4 weeks later, followed by every 12 weeks |
| Skelaxin (Metaxalone) Tablets   | Look                  | 800 mg                          | 800 mg orally three times per day or four times per day   |
|   |                       |                                 |   |
| Alera (Hydroquinone) Topical Emulsion   | Sound                 | 4%                              | 1 application to the affected area(s) twice daily   |
| <br>  |                       |                                 |   |
| Relera (Chlorpheniramine Maleate and Phenylephrine Hydrochloride) Extended-Release Tablets<br><br><i>Product has been discontinued. Unable to determine the date of discontinuation. Similar products are currently marketed.</i> | Look and Sound        | 8 mg/20 mg                      | ½ tablet or 1 tablet twice daily or three times per day   |

b(4)

b(4)

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| Product name with potential for confusion | Similarity to Stelara | Strength                        | Usual Dose   |
|---|-----------------------|---------------------------------|--|
| Stelara                                   | NA                    | 45 mg/0.5 mL and 90 mg per 1 mL | 45 mg (weight ≤ 100 kg) or 90 mg (weight > 100 kg) subcutaneously once and 4 weeks later, followed by every 12 weeks |
| _____                                     |                       |                                 |  |
|   |                       |                                 |  |

b(4)

**Appendix G: Products with overlap in strength, dose or achievable dose with multiple differentiating product characteristics**

| Product name with potential for confusion | Similarity to Stelara | Strength                        | Usual Dose (if applicable)   | Differentiating Product Characteristics (Stelara vs. Product)  |
|---|-----------------------|---------------------------------|--|--|
| Stelara                                   | NA                    | 45 mg/0.5 mL and 90 mg per 1 mL | 45 mg (weight ≤ 100 kg) or 90 mg (weight > 100 kg) subcutaneously once and 4 weeks later, followed by every 12 weeks | NA   |
| Starlix (Nateglinide) Tablets             | Look                  | 60 mg and 120 mg                | 60 mg or 120 mg orally three times per day before meals  | <i>Route of administration:</i><br>Subcutaneous vs. oral<br><br><i>Dosage form:</i> Injection vs. tablet<br><br><i>Frequency of administration:</i><br>Once and four weeks later followed by every 12 weeks vs. three times per day before meals |

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**Appendix H: Side-by-side product comparison of Stelara and Stalevo**

| <b>Product Comparison</b>          |   |  |
|------------------------------------|---|--|
| <b>Proprietary Name</b>            | <b>Proposed Proprietary Name</b><br>Stelara   | <b>Stalevo 50, Stalevo 75, Stalevo 100, Stalevo 125, Stalevo 150, and Stalevo 200</b>  |
| <b>Established Name</b>            | Ustekinumab   | Carbidopa, Levodopa and Entacapone   |
| <b>Dosage Form</b>                 | Injection   | Tablets  |
| <b>Strengths</b>                   | 45 mg/0.5 mL and 90 mg per mL   | Stalevo 50 (12.5 mg/50 mg/200 mg)<br>Stalevo 75 (18.75 mg/75 mg/200 mg)<br>Stalevo 100 (25 mg/100 mg/200 mg)<br>Stalevo 125 (31.25 mg/125 mg/200 mg)<br>Stalevo 150 (37.5 mg/150 mg/200 mg)<br>Stalevo 200 (50 mg/200 mg/200 mg) |
| <b>Indication of use</b>           | Treatment of adult patients (18 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy | Treatment of patients with idiopathic Parkinson's disease  |
| <b>Usual Dosage</b>                | 45 mg (weight ≤ 100 kg) or 90 mg (weight > 100 kg)  | 1 tablet or may be ordered by strength (e.g., 12.5 mg/50 mg/200 mg)  |
| <b>Route of Administration</b>     | Subcutaneous  | Oral   |
| <b>Frequency of Administration</b> | Once and 4 weeks later, followed by every 12 weeks  | Up to a maximum of 8 times per day (except for Stalevo 200 which is a maximum of 6 times per day)  |