

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-264**

**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: May 1, 2009

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Subject: Proprietary Name Review

Drug Name(s): Invega Sustenna (Paliperidone Palmitate) Injection  
25 mg, 50 mg, 75 mg, 100 mg and 150 mg

Application Type/Number: NDA 22-264

Applicant: Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

OSE RCM #: 2009-285

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

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## **EXECUTIVE SUMMARY**

This re-assessment of the proprietary name Invega Sustenna. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name Invega Sustenna, acceptable in OSE Review # 2008-117 dated August 5, 2008. Since the last review the Applicant has changed the stating dose from (b) (4) to 150 mg on treatment day 1, and 100 mg one week later.

Due to the change in starting dose DMEPA re-reviewed the previous names identified in OSE Review# 2008-117 dated August 5, 2008, and ten new names which were identified during this review, for their similarity to Invega Sustenna. The results of the Failure Mode Effects Analysis found that the proposed name, Invega Sustenna, is not vulnerable to name confusion that could lead to medication errors with any of the ten names. Thus, the Division of Medication Error Prevention and Analysis does not object to the use of the proprietary name, Invega Sustenna, for this product.

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

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

The proposed proprietary name, Invega Sustenna, was previously reviewed by DMEPA in 2008 when the NDA was first submitted under OSE Consult # 2008-117 without objection. As such, DMEPA will not reevaluate the modifier independent of the entire proposed proprietary name in this evaluation of the proposed name. Container labels and carton labeling were also provided to be evaluated from a medications errors perspective. Review comments on the labels and labeling will be provided under separate cover in a forthcoming review (OSE Review # 2009-286).

### **1.2 PRODUCT INFORMATION**

Invega Sustenna is the proposed name for paliperidone palmitate long-acting injection. Invega Sustenna is hydrolyzed to paliperidone, the active metabolite of risperidone. The mechanism of action of paliperidone is unknown, but it has been proposed that the therapeutic activity in schizophrenia is mediated through a combination of central dopamine Type 2 (D<sub>2</sub>) and serotonin Type 2 (5HT<sub>2A</sub>) receptor antagonism.

For patients who have never taken oral paliperidone or oral or injectable risperidone, it is recommended that the tolerability of paliperidone be established prior to initiating treatment with Invega Sustenna. The recommended initial dose of Invega Sustenna is 150 mg via intramuscular injection on treatment day 1 and 100 mg one week later, both administered in the deltoid muscle. The recommended subsequent monthly dose is 75 mg; which can be increased or decreased in a range of 25 mg to 150 mg based upon individual patient tolerability and/or efficacy. Following the second dose, monthly doses can be administered in either the deltoid or gluteal muscle. Invega Sustenna should be administered by a healthcare professional, slowly and deeply into the muscle.

The recommended needle size for administration into the gluteal muscle is the 1 1/2-inch, 22 gauge needle. Administration should be made into the upper-outer quadrant of the gluteal area, with injection sites alternated between the two gluteal muscles. The recommended needle size for injections in the deltoid muscle is determined by the patient's weight. For patients whose weight is greater than or equal to 90 kg, the 1 1/2 inch, 22 gauge needle is recommended. For those weighing less than 90 kg, the 1-inch, 23 gauge needle is recommended. Deltoid injections should be alternated between the two deltoid muscles.

Invega Sustenna will be supplied as a kit containing a pre-filled syringe and 2 safety needles (a 1 1/2-inch 22 gauge safety needle and a 1-inch 23 gauge safety needle) for injection. The pre-filled syringes contain 25 mg, 50 mg, 75 mg, 100 mg and 150 mg of paliperidone.

## 2 METHODS AND MATERIALS

This section describes the methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The objective for the assessment is to identify and remedy potential sources of medication error prior to drug approval. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>1</sup>

### 2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Invega Sustenna, 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 Agency.

For the proprietary name, Invega Sustenna, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held a Center for Drug Evaluation and Research (CDER) Expert Panel Discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). DMEPA normally conducts internal CDER prescription analysis studies. When provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.2). The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of the staff to anticipate the conditions of the clinical setting that the product is likely to be used in 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 drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage

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

<sup>2</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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>3</sup>

### **2.1.1 Search Criteria**

DMEPA staff considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter ‘I and 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>4,5</sup> Additionally, since omission of a modifier is cited in the literature as a common cause of medication errors<sup>6</sup>, the DMEPA staff consider ‘Invega Sustenna’ as a complete name as well as ‘Invega,’ the root name alone.

To identify drug names that may look similar to Invega Sustenna, the staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters for Invega and eight letters for Sustenna), upstrokes (three; capital letters ‘I’ and ‘S’, lower case letters ‘t’, downstrokes (one, lower case ‘g’), cross-strokes (one lower case ‘t’), and dotted letters (none). Additionally, several letters in Invega may be vulnerable to ambiguity when scripted, including the letter ‘I’ may appear as ‘J’, ‘L’; lower case ‘n’ may appear as a lower case ‘m’, ‘u’, ‘x’, ‘r’, ‘h’, or ‘s’; lower case ‘v’ may appear as lower case ‘r’ or ‘n’; lower case ‘e’ may appear as a lower case ‘l’ or ‘o’; lower case ‘g’ may appear as lower case ‘p’ or ‘q’; and lower case ‘a’ may appear as lower case ‘o’. Additionally, several letters in Sustenna may be vulnerable to ambiguity when scripted, including the letter ‘S’ may appear as upper case ‘G’; lower case ‘u’ may appear as lower case ‘n’ or ‘v’; lower case ‘s’ may appear as lower case ‘r’ or ‘n’; lower case ‘t’ may appear as lower case ‘l’ or ‘x’; lower case ‘e’ can appear as lower case ‘l’ or ‘i’; lower case ‘n’ or ‘nn’ may appear as a lower case ‘m’, ‘n’, ‘v’ or ‘w’; and lower case ‘a’ may appear as ‘o’. As such, the staff also considers these alternate appearances when identifying drug names that may look similar to Invega Sustenna.

When searching to identify potential names that may sound similar to Invega Sustenna, the DMEPA staff search for names with similar number of syllables (three and three), stresses (IN-veg-ah or in-VEG-AH and SUST-en-nah or Sus-ten-AH), and placement of vowel and consonant sounds. Additionally, the staff also considers that pronunciation of parts of the name can vary such as ‘In-’ may sound like ‘En’. The Applicant’s intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

The DMEPA staff also considers the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately

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<sup>3</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

<sup>4</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>5</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

<sup>6</sup> Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

determine the use of the product in the clinical practice setting. For this review, DMEPA staff were provided with the following information about the proposed product: proposed proprietary name (Invega Sustenna), established name (paliperidone palmitate), proposed indication of use (schizophrenia), strength (25 mg, 50 mg, 75 mg, 100 mg and 150 mg), dose (150 mg on treatment day 1, then 100 mg one week later, subsequent doses of 25 mg, 50 mg, 75 mg, 100 mg, or 150 mg are once a month), frequency of administration (monthly), route (intramuscularly) and dosage form of the product (prefilled syringe for injection). Appendix A provides a more detailed listing of the product characteristics that DMEPA staff generally take into consideration.

Lastly, DMEPA staff considers the potential for the proposed 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, these broader safety implications of the name are considered and evaluated throughout this assessment and DMEPA staff provides additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

#### **2.1.1.1 Database and Information Sources**

The proposed proprietary name, Invega Sustenna, was provided to the DMEPA staff to conduct a search 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 Invega Sustenna using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, DMEPA staff used 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 the multiple safety evaluators were then pooled and presented to the CDER Expert Panel.

#### **2.1.1.2 FDA Expert Panel Discussion**

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the product and the proprietary name. The Expert Panel is composed of the Division of Medication Errors Prevention and Analysis (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). Potential concerns regarding drug marketing and promotion related to the proposed name are also discussed.

The pooled results of DMEPA staff were presented 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 Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

#### **2.1.2 Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies his/her individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Mode and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>7</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential

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<sup>7</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

for a proposed name to be confused with another drug name as a result of the name confusion and 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 look- or sound-alike 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 Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. 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 evaluation, and studies, and identifies potential failure modes by asking:

***“Is the name Invega Sustenna 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 name, Invega Sustenna, 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 and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking:

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

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated 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 that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMEPA will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator’s Risk Assessment:

1. 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 trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. 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)].

3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. DMEPA identifies a potential source of medication error within the proposed proprietary name. 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.

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 is awarded approval first has the right to the use the name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then DMEPA will object to the use of the proprietary 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 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, Joint Commission, and ISMP, who have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, 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, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken 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 the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, 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).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used 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, and so DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

## **3 RESULTS**

### **3.1 PROPRIETARY NAME RISK ASSESSMENT**

#### ***3.1.1 Database and Information Sources***

The search yielded a total of nineteen names as having some similarity to the name 'Invega Sustenna' or either of the name components 'Invega' or 'Sustenna'.

Ten of the nineteen names were thought to look like Invega or Sustenna. These include Invanz, Invagesic, Lovaza, Inspira, (b) (4), Indinavir Sulfate, Invirase, Sustagen, Sustaire, Sufenta. Five of the nineteen names (Senna, Henna, Systane, System and Systane Free) were thought to sound like Sustenna. The remaining four names, Invega, Sustiva, Susano and (b) (4), were thought to look and sound similar to Invega Sustenna.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the name, Invega Sustenna, as of March 11, 2009.

#### ***3.1.2 Expert Panel Discussion***

The Expert Panel reviewed the pool of names identified by DMEPA staff (see section 3.1.1. above) and did not note any additional names thought to have orthographic or phonetic similarity to Invega Sustenna.

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

#### ***3.1.3 Safety Evaluator Risk Assessment***

Nine of the names identified for this review were evaluated in DMEPA's previous review for the name Invega Sustenna (OSE Review 2008-117). Although the initial recommended dose has changed (from (b) (4) to 150 mg), this change does not impact the analysis of the names previously reviewed. The remaining ten newly identified names were analyzed to determine if the drug names could be confused with Invega Sustenna and if the drug name confusion would likely result in a medication error.

Failure mode and effect analysis was then applied to determine if the potential name could potentially be confused with any of the ten names and lead to medication errors. This analysis determined that the name similarity between Invega Sustenna and the identified names was unlikely to result in medication errors with any of the ten products identified for the reasons presented in Appendices C-F.

## **4 DISCUSSION**

### **4.1 PROPRIETARY NAME RISK ASSESSMENT**

Nineteen names were evaluated for their potential similarity to the proposed name, Invega Sustenna. The findings of our FMEA indicates that the proposed name is not vulnerable to name confusion that could lead to medication errors for the reasons outlined in Appendices C through F.

## **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Invega Sustenna, is not vulnerable to name confusion that could lead to medication errors. Thus the Division of Medication Error Prevention and Analysis has no objection to the use of the proprietary name, Invega Sustenna, for this product. However, if **any** of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention and Analysis rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. Additionally, if the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

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

We would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy DMEPA on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Abolade Adeolu, project manager, at 301-796-4264.

### **5.2 COMMENTS TO THE APPLICANT**

#### **5.2.1 *Proprietary Name***

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

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

If **any** of the proposed product characteristics as stated in your submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

## 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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

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

Drug Facts and Comparisons is a compendium organized by therapeutic course; 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>)

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

Provides information regarding patent and trademarks.

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

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. 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))**

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))**

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

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

List contains all the recognized USAN stems.

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

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))**

A web-based searchable version of the Drug Information Handbook.

**16. Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

DMEPA staff consider 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. The 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* 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 their 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). 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 practice.

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

		scripting letters Overlapping product characteristics	
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

**Appendix B:** Product names identified in the previous review for Invega Sustenna

<b>Product name</b>	<b>Similarity to Invega Sustenna</b>
Sustagen	Look
Sustaire	Look
(b) (4)	Look
Invirase	Look
Sufenta	Look and Sound
Systane	Look
Invega	Look and Sound
Sustiva	Look
(b) (4)	Look

**Appendix C:** Products that lack orthographic and phonetic similarity to Invega Sustenna

<b>Product name with potential for confusion</b>	<b>Similarity to Invega Sustenna</b>
Lovaza	Look
Inspra	Look
Indinavir Sulfate	Look
Henna	Sound
Systane Free	Sound
Susano	Look and Sound

**Appendix D:** Names of products marketed or trademarked in foreign countries

Name	Similarity to Invega Sustenna	Country
System (Estradiol)	Look and Sound	Mexico

**Appendix E:** Products with no overlap in strength and dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
<b>Invega Sustenna</b>	<b>N/A</b>	<b>25 mg, 50mg, 75 mg, 100 mg and 150 mg</b>	<b>Inject 150 mg on day 1 and 100 mg one week later. Subsequent monthly maintenance doses ranging from 25 mg to 150 mg (based on tolerability and/or efficacy).</b>
Senna	Look	176 mg/5 mL syrup; 8.8 mg/5 mL syrup; 187 mg tablet; 8.6 mg (concentrate) tablet	Syrup: 1 teaspoonful twice daily  Tablets: 1 to 2 tablets twice daily

(b) (4)

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

Product name with potential for confusion	Similarity to Invega Sustenna	Strength	Usual Dose (if applicable)	Differentiating Product Characteristics (Invega Sustenna vs. Product)
Invega Sustenna	N/A	25 mg, 50 mg, 75 mg, 100 mg and 150 mg	Inject 150 mg on day 1 and 100 mg one week later. Subsequent monthly maintenance dose ranging from 25 mg to 150 mg (based on tolerability and/or efficacy).	N/A
Invagesic	Look	(Each tablet contains) Aspirin 325 mg; Caffeine 30 mg; Orphenadrine 25 mg	1 to 2 tablets three to four times daily	Frequency: 150 mg initially followed by 100 mg one week later then 75 mg once a month vs. three to four times a day.  Route of administration: Intramuscular injection vs. oral  Dosage form: Lyophilized powder for injection vs. tablet

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/s/

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