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
To:	Thomas Laughren, M.D., Director Division of Psychiatry Products
Through:	Laura Pincock, PharmD, Acting Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Diane C. Smith, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
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.*****

CONTENTS

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_2) and serotonin Type 2 ($5HT_{2A}$) 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 injections 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. [1]

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. [2] 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

---

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

[2] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.