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APPLICATION NUMBER:
201655Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: September 30, 2011

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Drug Name(s): Opana ER (Oxymorphone Hydrochloride) Extended-release Tablets
5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg

Application Type/Number: NDA 201655

Applicant/sponsor: Endo Pharmaceuticals Inc.

OSE RCM #: 2011-2445

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Opana ER, from a safety perspective.

1.1 REGULATORY HISTORY

Opana ER (Oxymorphone Hydrochloride) extended-release tablets (NDA 021610) was approved on June 22, 2006. The Applicant submitted NDA 201655 on July 7, 2010 to propose an abuse-deterrent formulation of oxymorphone extended-release tablets. (b) (4)

However, the Applicant now intends to replace the currently marketed formulation approved under NDA 021610 with the new formulation in NDA 201655 and therefore, proposes to continue using the Opana ER proprietary name per agreement with the Division of Analgesics, Anesthetics, and Addiction Products during an Endo/FDA teleconference held January 5, 2011. On January 7, 2011, NDA 201655 received a Complete Response due inability to establish bioequivalence of the proposed product to the reference product (NDA 021610). The Applicant proposes to establish bioequivalence in this submission.

1.2 PRODUCT INFORMATION

The Applicant designed the proposed product (NDA 201655) to be physically harder than the referenced formulation (NDA 021610) to serve as an abuse deterrent. Both products share the same product characteristics, with the exception that the proposed abuse deterrent formulation requires instructions to ensure complete swallowing. Once bioequivalence is established, there is no major safety issue with switching patients from the referenced formulation of Opana ER and the proposed abuse-deterrent formulation of Opana ER.

Opana ER has a proposed indication for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. Opana ER tablets are to be swallowed whole and not to be broken, chewed, dissolved, or crushed. Opana ER tablets must be taken one tablet at a time, with enough water to ensure complete swallowing. Opana ER is to be administered every 12 hours with the following dose recommendations:

- Opioid naive patients - 5 mg every 12 hours
- Conversion from Opana to Opana ER – half the patient's total daily oral Opana dose as Opana ER, every 12 hours.
- Conversion from parenteral - administer 10 times the patient's total daily parenteral oxymorphone dose as Opana ER in two equally divided doses [(intravenous dose x 10) divided by 2].
- Conversion from other oral opioids – follow Dose Conversion table in insert labeling.

Opana ER is available as 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg tablets in bottles of 100 tablets. Opana ER should be stored at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

2 METHODS AND DISCUSSION

With the exception of the proposed abuse deterrent properties of the proposed product (201655), both the proposed product (NDA 201655), and the currently marketed product (NDA 021610) share the same product characteristics. Therefore, we reviewed previous OSE Reviews for Opana ER for medication errors involving proprietary name confusion. Additionally, we considered whether the new instructions to ensure complete swallowing could be safely managed under the same proprietary name Opana ER.

2.1 PROPRIETARY NAME CONFUSION

OSE Review 2010-2081 documented 5 reports of wrong drug errors involving proprietary name confusion with Opana 10 mg and Opana ER 10 mg. Confusion between immediate- and extended-release formulations of the same product is likely to occur when there are overlapping strengths and the products share the same root name (*Opana*). To minimize this issue, DMEPA recommends Applicants develop extended-release products that do not have overlapping strengths with the immediate-release formulation. However, because the Applicant developed Opana ER with an overlapping strength (Opana 10 mg and Opana ER 10 mg), we recommended labeling differentiation to minimize wrong drug errors during the pre-marketing review of NDA 021610 and in review of a prior approval supplement in OSE Reviews 03-0105-3 and 2008-43, respectively. In this submission NDA 201655, the Applicant has further enhanced the differentiation of the container labels of Opana ER compared to Opana and this should help to further reduce confusion.

In addition, labeling review for this application, OSE Review 2011-2466 dated September 2, 2011, there were no AERS reports involving proprietary name confusion with Opana ER and other drugs products.

Furthermore, the Agency has previously approved the nomenclature approach using the proprietary name of the referenced formulation for the proposed abuse deterrent formulation, in which both products were bioequivalent and shared the same product characteristics.

2.2 FORMULATION DIFFERENCES

The proposed formulation differs from the referenced formulation in that the proposed formulation is designed to make the tablet harder to resist crushing or breaking. There are approved products that are designed similarly to resist crushing or breaking, such as the reformulated OxyContin^{***} (Oxycodone Hydrochloride) Extended-release Tablets and the recently approved Oxecta^{***} (Oxycodone Hydrochloride, USP) Tablets. There have been reports of difficulty swallowing the reformulated OxyContin^{***} primarily in patients with underlying gastrointestinal disorders. Subsequently, the labeling of OxyContin^{***} and Oxecta^{***} provides instructions in the insert labeling and Medication Guide to prevent swallowing difficulty. Thus, we find it acceptable to communicate the new instructions to ensure complete swallowing of the proposed abuse deterrent formulation of Opana ER through labeling, similar to the currently marketed products, OxyContin^{***} and Oxecta^{***}.

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