CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201655Orig1s000

OTHER 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

PATIENT LABELING REVIEW

Date:	October 03, 2011
To:	Bob Rappaport MD, Director **Division of Anesthesia, Analgesia and Addiction Products (DAAAP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Acting Team Leader, Patient Labeling Reviewer **Division of Risk Management (DRISK)** Barbara Fuller, RN, MSN, CWOCN Acting Team Leader, Patient Labeling Reviewer **Division of Risk Management**
From:	Steve L. Morin, RN, BSN, OCN Patient Labeling Reviewer **Division of Risk Management**
Subject:	DRISK Review of Patient Labeling (Medication Guide)
Drug Name (established name):	OPANA ER (oxymorphone hydrochloride)
Dosage Form and Route:	Extended-Release tablets, CII
Application Type/Number:	NDA 201-655
Applicant:	Endo Pharmaceuticals Inc.
OSE RCM #:	2011-2447

1 INTRODUCTION

This review is written in response to a request by the Division of Anesthesia, Analgesia and Addiction Products (DAAAP) for the Division of Risk Management (DRISK) to review the Applicant's proposed Medication Guide (MG) for OPANA ER (oxymorphone hydrochloride) Extended-Release tablets. The proposed indication for OPANA is for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

On July 7, 2010 Endo Pharmaceuticals submitted New Drug Application (NDA) 201-655 for (b) (4) (oxymorphone hydrochloride) Extended-Release Tablets. . DRISK completed a review of the proposed Medication Guide on December 22, 2010. On January 6 2011 Endo Pharmaceuticals (b) (4) submitted a request for the proposed proprietary tradename OPANA ER. On January 7, 2011 Endo received a Complete Response for bioequivalence study deficienciesOn June 13, 2011 Endo Pharmaceuticals submitted a Class 2 Resubmission for OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets.

The proposed REMS was reviewed by DRISK and submitted to DAAAP under separate cover on August 31, 2011.

2 MATERIAL REVIEWED

- Draft OPANA ER (oxymorphone hydrochloride) Extended-Release tablets Medication Guide (MG) received on June 13, 2011and sent to DRISK on September 19, 2011.
- Draft OPANA ER (oxymorphone hydrochloride) Extended-Release tablets Prescribing Information (PI) received June 13, 2011 and sent to DRISK on September 19, 2011.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the MG the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss.* The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We have reformatted the MG document using the Verdana font, size 11.

In our review of the MG we have:

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the Prescribing Information (PI)

- removed unnecessary or redundant information
- ensured that the MG meets the Regulations as specified in 21 CFR 208.20
- ensured that the MG meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The MG is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DRISK on the correspondence.
- Our annotated versions of the MG are appended to this memo. Consult DRISK regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the MG.

Please let us know if you have any questions.

16 pages of draft labeling has been withheld in full as

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/s/

STEVE L MORIN
10/03/2011

LASHAWN M GRIFFITHS
10/03/2011

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