CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

REMS

NDA 22-272
OxyContin® (oxycodone hydrochloride controlled-release) Tablets

Opioid Agonist

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

Goal 1: To inform patients and healthcare professionals about the potential for abuse, misuse, overdose, and addiction of OxyContin®

Goal 2: To inform patients and healthcare professionals about the safe use of OxyContin®

II. REMS ELEMENTS

A) Medication Guide

In accordance with 21 CFR 208.24, a Medication Guide will be dispensed with each OxyContin® prescription. Purdue Pharma L.P. will ensure that the Medication Guide is available for distribution to patients receiving a prescription for OxyContin® by providing sufficient numbers to distributors and authorized dispensers.

1. One copy of Full Prescribing Information, which includes the Medication Guide, will be packaged with each bottle of OxyContin®.
2. Two separate additional Medication Guides will also be packaged with each bottle of OxyContin®.
3. Per 21CFR 208.24(d) the label of each container or package of OxyContin® will include a prominent and conspicuous statement:

   a) instructing authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed (eg, “Attention Dispenser: Accompanying Medication Guide must be provided to each patient upon dispensing”), and

   b) stating how the Medication Guide is provided.

4. Medication Guides will also be available via Purdue Pharma L.P. Field Sales representatives, through an Internet presence, and from Purdue's Medical Services Department (1-888-726-7535).

Please see appended Medication Guide.

B. Elements to Assure Safe Use

1. Healthcare providers who prescribe OxyContin® will receive training.

   a. Purdue will ensure that training will be provided to healthcare providers who prescribe OxyContin®. To become trained, each prescriber will be provided with the OxyContin® Educational materials.

      The Training includes the following:

      i) Proper patient selection;

      ii) Appropriate OxyContin® dosing and administration;

      iii) General principles of safe opioid use, including information about opioid abuse and how to identify patients who are at risk for addiction;

      iv) Potential abuse, misuse, overdose and addiction from exposure to opioids, including OxyContin®;

      v) Risks of OxyContin®, including:

         1. The risk of overdose caused by exposure to an essentially immediate-release form of oxycodone by consuming broken, chewed, crushed or dissolved OxyContin® tablets;

         2. The risk of addiction from exposure to OxyContin®; and

         3. The risk of overdose in patients who have not developed tolerance to the sedating or respiratory-depressant effects of opioids from exposure to a single dose of OxyContin greater than 40 mg;

      vi) Information to counsel patients and caregivers on the need to store opioid analgesics safely out of reach of children and household acquaintances and the need to properly dispose of unused drugs when no longer needed by the patient; and

      vii) Importance of providing each patient a Medication Guide with each prescription and instructing the patient to read the Medication Guide.

   b. Purdue will ensure that at least 3 weeks prior to first availability of OxyContin® to healthcare professionals, a Dear Healthcare Professional letter will be mailed to prescribers most

experienced in treating chronic pain with opioid agonists, including pain specialists, physiatrists, and primary care physicians. This letter is designed to convey and reinforce the risks of abuse, misuse, overdose and addiction of OxyContin® as well as the need to complete the OxyContin® REMS Educational Program. This letter will be available on the Purdue website (www.oxycontinrems.com) for 1 year from the date of mailing.

c. The mailings will include the following OxyContin® REMS Educational Program materials:

i) OxyContin® Medication Guide

ii) Prescribing OxyContin® Tablets CII: A Guide for Healthcare Providers

iii) OxyContin® Education Confirmation Form

d. Additional printed educational material will be available through field-force distribution and by calling the toll-free number at Purdue (1-888-726-7535).

e. The educational material will also be available for download at www.oxycontinrems.com.

f. Purdue will maintain a list of all prescribers who have completed the OxyContin® REMS Educational Program.

Prescribers will be re-trained every two years or following substantial changes to the OxyContin® REMS. Substantial changes may include changes in the OxyContin® Full Prescribing Information, OxyContin® Medication Guide, or OxyContin® REMS that require substantial modification of the educational materials.

The following materials are part of the REMS and are appended:

- Dear Healthcare Professional Letter
- Medication Guide
- The Healthcare Provider Guide, "Prescribing OxyContin® Tablets CII: A Training Guide for Healthcare Providers"
- OxyContin® Education Confirmation Form

C. Implementation System

Because OxyContin® can be approved without the Elements to Assure Safe Use described under FDCA 505-1(f)(3) (B), (C), and (D) of the Act, an implementation system is not required.

D. Timetable for Submission of Assessments

Purdue Pharma L.P. will submit REMS Assessments to FDA every 6 months for the first year from the date of approval of the REMS and annually thereafter. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment. Purdue L.P. will submit each assessment so that it will be received by the FDA on or before the due date.

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