CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

RISK ASSESSMENT and RISK MITIGATION 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:	June 18, 2010
To:	Bob Rappaport, MD, Director Division of Anesthesia and Analgesia Products (DAAP)
Through:	Mary Willy, MPH, Deputy Director Division of Risk Management (DRISK)
From:	Gita A. Toyserkani, Pharm.D., MBA, Senior Drug Risk Management Analyst, Acting TL Mary Dempsey BS, Coordinator for Risk Management Programs, DRISK
Subject:	Prior Approval REMS Modification
Drug Name(s):	OxyContin Tablets (oxycodone hydrochloride controlled-release)
Application Type:	NDA 022272
Applicant/sponsor:	Purdue Pharma L.P.
OSE RCM #:	2010-1354

1 Background

The Division of Anesthesia and Analgesia Products (DAAP) requested that the Division of Risk Management (DRISK) review the OxyContin (oxycodone hydrochloride controlled-release) tablets Prior Approval REMS Modification Supplement for New Drug Application (NDA 022272) submitted by Purdue Pharma L.P. on June 10, 2010. This supplemental new drug application provides for revisions to the Training Guide for Healthcare Providers, boxed warning, table of contents, references, removal of website reference, and upper/lower case text.

The OxyContin (oxycodone hydrochloride controlled-release) tablets REMS was approved April 5, 2010 with the following elements:

- Medication Guide
- Elements to Assure Safe Use
    - Healthcare provider training
    - Dear Healthcare Professional letter mailed at least three (3) weeks prior to first availability of Oxycontin
    - Prescriber re-training every two (2) years
- Timetable for Submission of Assessment

2 Material Reviewed

- April 2, 2010 Purdue submitted REMS Supporting Document
- April 5, 2010 Oxycontin REMS approval
- June 10, 2010 Purdue submitted Prior Approval REMS Modification

3 Proposed REMS Elements

The Oxycontin June 10, 2010 submission provides the proposed REMS modification, Medication Guide, Dear Healthcare Professional Letter, Healthcare Provider Training Guide, and Education Confirmation Form. The REMS Supporting Document is not included in this submission. The product is in pre-launch development and not currently marketed; therefore, it is reasonable to state that insufficient time has passed since the REMS approval to provide a meaningful assessment. The cover letter of the June 10, 2010 submission states the following:

> "The approved REMS Supporting Document remains unchanged and is identical to the version submitted on April 2, 2010
>
> Herein we are submitting the revised REMS…which include revisions only to the Training Guide for Healthcare Providers. In our view, these revisions are minor and do not change the content, but rather improve the document quality. For ease of review, the revisions are outlined below:
> - "(oxycontin hydrochloride controlled release) added to headline page and the indication pg 4
> - Boxed warning from approved FPI replaced current version that was developed for use in HCP Guide. This ensures that a consistent official black box warning is used in the FPI and Training Guide [this is the only one that should be in circulation]
> - "Full Prescribing " and Boxed Warning- Uppercased throughout the document

- Table of Contents (TOC moved to page 3 after black boxed warning, This ensures that the TOC precedes the Introduction section, rather than after the Introduction where it is currently located
- Removed reference to website on page 11 as not relevant to section
- References reordered to be in numerical sequence (previously jumped from #1 to # 7)."

4 Discussion and Conclusion

DRISK performed a comparison of the June 10, 2010 submitted proposed REMS and Medication Guide to the approved Oxycontin REMS and Medication Guide and found then to be identical. The revisions to the Healthcare Provider Training Guide proposed by Purdue are acceptable.

5. Recommendation

Approve the REMS modification as submitted June 10, 2010.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22272	SUPPL-5	PURDUE PHARMA INC	OXYCONTIN

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY J DEMPSEY
06/18/2010

MARY E WILLY
06/19/2010
I concur

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.