CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 22-272

Trade Name:	Oxycontin, Tablets (Controlled Release)
Generic Name:	Oxycodone hydrochloride controlled-release
Sponsor:	Purdue Pharma
Approval Date:	4/5/10
Indications:	For the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**x**
Other Action Letters	**x**
Labeling	**x**
REMS	**x**
Summary Review	**x**
Officer/Employee List	**x**
Office Director Memo	
Cross Discipline Team Leader Review	**x**
Medical Review(s)	**x**
Chemistry Review(s)	**x**
Environmental Assessment	
Pharmacology Review(s)	**x**
Statistical Review(s)	**x**
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	**x**
Other Reviews	**x**
Risk Assessment and Risk Mitigation Review(s)	**x**
Proprietary Name Review(s)	**x**
Administrative/Correspondence Document(s)	**x**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022272 **NDA APPROVAL**

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

Attention: Craig Landau, M.D.
CMO & VP Clinical, Medical & Regulatory Affairs

Dear Dr. Landau:

Please refer to your new drug application (NDA) dated, received November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets.

We acknowledge receipt of your submissions dated November 30, and December 19, 20 and 21, 2007, January 14, February 8, 12, 14 (2), and 15 (2), March 7, 10, 14, 18, 25 (2), and 27, April 11 (2) and 23, May 7, August 20, September 26, October 30, November 11 and 20, and December 5, 8, and 10, 2008, and March 30, May 18, June 2, 10, and 16, July 13 and 24, August 7, September 18, October 6 and 9, and November 4, 6, 17, 19, and 23, December 16 and 22 2009, and February 5, and 24, March 11, 25, 26, and 31, and April 2, 2010.

The February 5, 2010, submission constituted a complete response to our December 30, 2009, action letter.

This new drug application provides for the use of OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, for treatment of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 31, 2010.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please resubmit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert and Medication Guide. For administrative purposes, please designate this submission, "**SPL for approved NDA 022272**."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your March 31, 2010, submission containing final printed carton and container labels.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

POSTMARKETING REQUIREMENTS UNDER 505(o)

As you were informed in our December 30, 2009, Complete Response Letter, FDA has determined that you are required to conduct postmarketing studies of OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets to assess the known serious risks of OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets, in particular, whether the changes made to the OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets formulation that are the subject of this application and which are intended to deter misuse and abuse actually result in a decrease in the risks of misuse and abuse, and their consequences.

Specifically, we have determined that you are required, pursuant to section 505(o)(3) of the FDCA, to conduct epidemiological studies to address whether the changes made to the OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets formulation that are the subject of this application result in a decrease in misuse and abuse, and their consequences: addiction, overdose, and death.

We acknowledge receipt of your proposal, included in your February 5, 2010, resubmission to this application, that contains brief descriptions of possible postmarketing studies to fulfill this requirement. Because of design and methodology challenges, we continue to be concerned that the proposed studies will not successfully capture the necessary information that will allow us to assess the impact, if any, attributable to the change in the OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets formulation. Therefore, we will continue discussion of your postmarketing study proposals at an advisory committee meeting in the fall of 2010 on the design and methodology of the proposed studies.

For the study to be conducted first, you must submit the final protocol and the timetable for completion of the study by January 31, 2011. Likewise, for the study to be conducted last, you must submit the final protocol and timetable for completion of the study by March 1, 2011.

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.