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Approval Package for:

APPLICATION NUMBER:

022272Orig1s027

Trade Name:	OXYCONTIN extended-release tablets
Generic Name:	oxycodone hydrochloride
Sponsor:	Purdue Pharma L.P.
Approval Date:	August 13, 2015
Indication:	This Prior Approval supplemental application proposes revisions to the Package Insert to include language for the use in the pediatric population and provides for updates to the approved risk evaluation and mitigation strategy (REMS) for OXYCONTIN.

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APPROVAL LETTER

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022272/S-027

SUPPLEMENT APPROVAL

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

Attention: Beth Connelly
Associate Director, Regulatory Affairs

Dear Ms. Connelly:

Please refer to your supplemental New Drug Application (sNDA) dated December 8, 2014, received December 10, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for OXYCONTIN (oxycodone hydrochloride) extended-release tablets.

We acknowledge receipt of your amendments dated April 3; May 11, 14, and 18; June 2, 3, 8, and 25; and July 13, 15 and 31, 2015.

This Prior Approval supplemental application proposes revisions to the Package Insert to include language for the use in the pediatric population and provides for updates to the approved risk evaluation and mitigation strategy (REMS) for OXYCONTIN.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the patient package insert and Medication Guide, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

Since OXYCONTIN was approved on April 5, 2010, we have become aware of clinical trial results in opioid-tolerant pediatric patients primarily aged 11-17. During the trial, there were two patients (an 11 year old female and a 15 year old female) with treatment-emergent clinically significant oxygen desaturations. Additionally, there were four patients in the total population (two each in the 6-11 age group and 12-17 age group) that experienced the treatment-emergent adverse event of "oxygen saturation decreased." We have also become aware of a study in the published literature describing the frequency of unintentional overdose with opioids in children covered by Tennessee Medicaid. In this study, designed to develop coding algorithms to identify

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