CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022272Orig1s027

CHEMISTRY REVIEW(S)

OFFICE OF LIFE CYCLE PRODUCTS
DPMA I, BRANCH I

Review of Chemistry, Manufacturing, and Controls

Clinical Review Division: Analgesic, Anesthesia and Addiction Products (HFD-510)

NDA#: 22-272	**REVIEW#.** 1	**REVIEW DATE:**	5/10/2015
SUBMISSION TYPE	**DOCUMENT DATE**	**CDER DATE**	**ASSIGNED**
S-027 (Efficacy)	12/10/2014	12/10/2014	05/08/2015
AMENDMENT	**PDUFA GOAL**		
04/02/2015	06/10/2015		
05/06/2015			

NAME & ADDRESS OF APPLICANT:

Purdue Pharma L.P.
201 Tresser Blvd
Stamford, CT 06901-3431

Beth Connelly, Associate Director, Regulatory Affairs
Phone: 203-588-7289
FAX: 203-588-6229

DRUG PRODUCT NAME

Proprietary: OxyContin® Tablets
Nonproprietary/USAN: oxycodone HCl extended release tablets

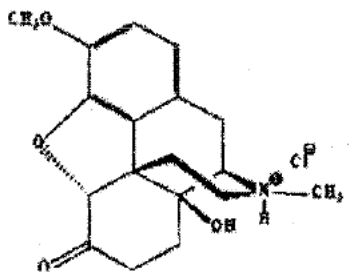
PHARMACOLOGICAL CATEGORY/INDICATION: Management of severe pain

DOSAGE FORM: Extended Release Tablet
STRENGTH: 10, 15, 20, 30, 40, 60 and 80 mg

ROUTE OF ADMINISTRATION: Oral
DISPENSED: X Rx ___ OTC
SPECIAL PRODUCTS: ___ Yes X No

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT:

Chemical Name: 4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride
Molecular Formula: $C_{18}H_{21}NO_4 \cdot HCl$
Molecular Weight: 351.82



PROVIDES FOR: (1) Labeling changes based on the pediatric studies to fulfill the Pediatric Written Request #3, Amendment #2; (b) (4)

REMARKS/COMMENTS:

In the supplement, the applicant submitted the Pediatric Study Reports to support the requested pediatric exclusivity. The supplement also provides for the labeling changes based on the clinical studies in accordance with the November 14, 2011 Written Request #3, Amendment #2.

The focus of this CMC review is (b) (4)

(b) (4)

Reference ID: 3810536

(b) (4)

[redacted]

CONSULT REVIEWS: N/A

COMMENTS/REQUESTS TO BE CONVEYED TO APPLICANT: N/A

CONCLUSIONS & RECOMMENDATIONS:

Based on the information provided by the applicant, it appears that Purdue Pharma has made [redacted] (b) (4)

(see attached electronic signature page)

Zedong Dong -S

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Zedong Dong, Ph.D.
Quality Assessment Lead (Acting)

Ramesh Raghavachari -S

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Date: 2015.05.11 11:30:57 -04'00'

Ramesh Raghavachari, Ph.D.
Chief, Branch I

cc: Orig. NDA#22272
OLDP/DPMA I/RRAGHAVACHARI
OLDP/DPMA I/ZDONG

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

/s/

MARY GRACE LUBAO
08/24/2015