CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272Orig1s014

OTHER REVIEW(S)

Labeling Review for Regulatory Action

Date	(electronic stamp)
From	Sharon Hertz, M.D.
Subject	Deputy Division Director Summary Review
NDA#/ Supplement #	022272/S-014
Applicant Name	Purdue Pharma
Date of Submission	September 12, 2012
PDUFA Goal Date	April 14, 2012
Proprietary Name / Established (USAN) Name	OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets
Dosage Forms / Strength	Tablet
Proposed Indication(s)	For the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Introduction

This supplemental application proposes the addition of labeling language describing the results of pre- and post-marketing data from in vitro and in vivo abuse potential studies to the DRUG ABUSE AND DEPENDENCE section, (b) (4) The material intended to support of the proposed labeling changes were submitted in the NDA and to IND 029038. A review of the studies intended to support the labeling changes was conducted by Dr. Pamela Horn as appended to the review by Dr. Bob Rappaport, dated February 10, 2013. Dr. Horn reviewed the following material:

IND 29038

- Abuse liability and pharmacokinetic studies
  - CSS reviews of studies OTR-1016, 1018, 1019, 1021, and 1022, DARRTS, 9/21/12
  - Statistical review of study OTR-1018, DARRTS, 8/20/12
  - Clinical Pharmacology review of studies OTR-1016, 1018, and 1021, DARRTS, 9/20/12
  - Study reports OTR-1016, 1018, 1019, 1021, and 1022, submitted to IND 9/17/10
  - Pharmacy instruction manuals OTR-1018 and 1021

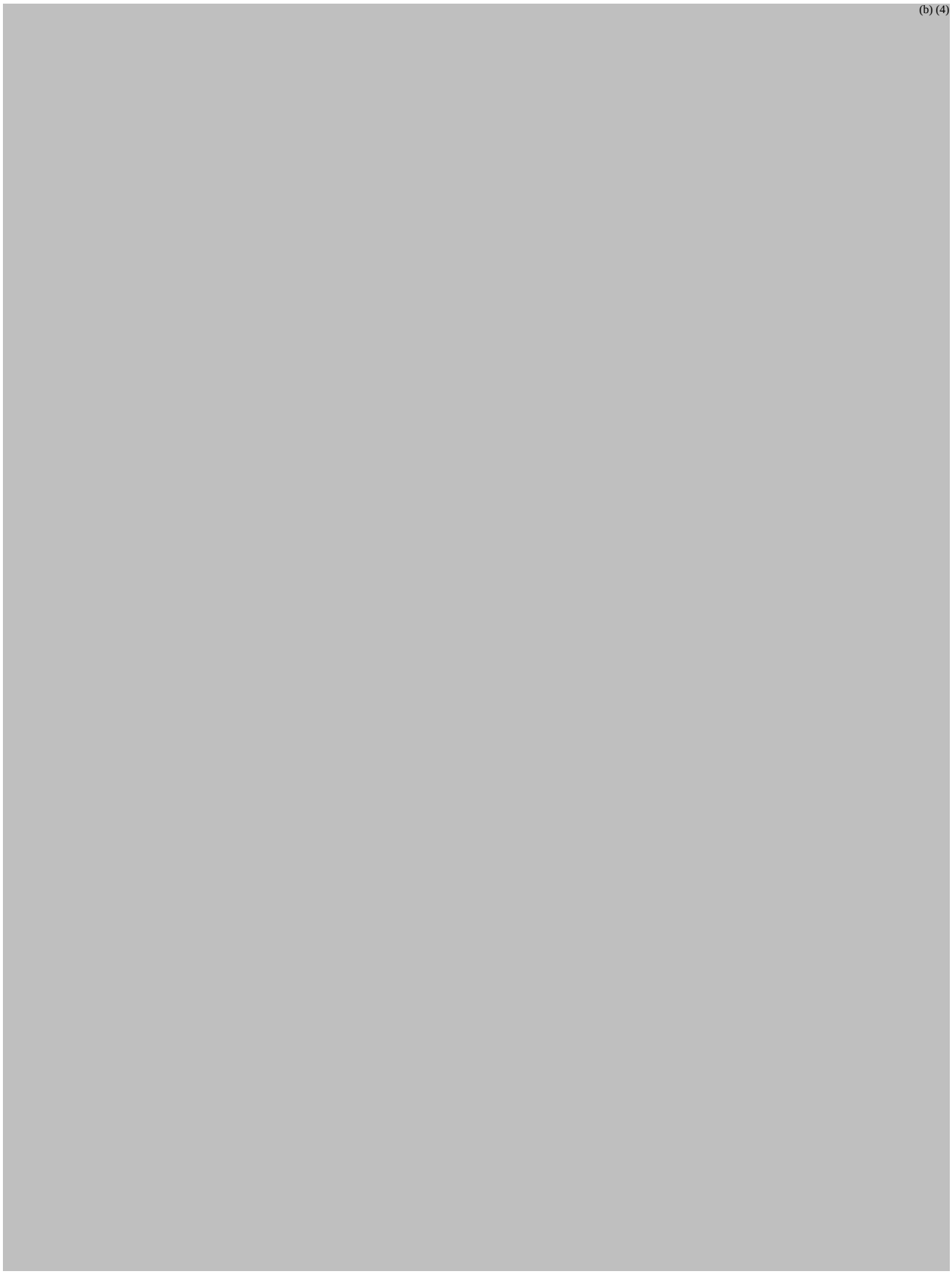
NDA 22272:

- In vitro studies: CSS review of the following documents, DARRTS, 9/4/09
  - Comprehensive In Vitro Testing of the Controlled-Release Properties of New OCR Tablets After Physical and Chemical Manipulation – Summary Report

- Comprehensive in Vitro Testing of the Controlled-Release Properties of New OCR Tablets After Physical and Chemical Manipulation – Complete Dataset Appendix
- Evaluation of the Resistance to Physical and Chemical Manipulation of Oxycodone HCl (10, 15, 20, 30, 40, 60 and 80 mg) TR Tablets Compared to Currently Marketed OxyContin (10, 15, 20, 30, 40, 60 and 80 mg)
- Protocol for Creating Particle Size Fractions by Crushing and Milling Extended Release Oxycodone HCl Tablets - OxTR In Vitro Testing Plan - Experiments 2a, b and 5a, b, c
- Protocol TTP-PMP-M0043.00 - "Simple Extraction: pH-Dependent API Release Study for Extended Release Oxycodone HCl Tablets"
- Protocol for Smoking (Inhalation) Testing of Physically Manipulated Extended Release Tablets Containing Oxycodone HCl
- Validation Protocol for Simple Extraction Testing of Physically Manipulated Extended Release Tablets Containing Oxycodone HCl

The applicant proposed the changes to Section 9 Drug Abuse and Dependence as shown in the following table. The labeling language is in the left column and the support for the language is in the right column.

(b) (4)



(b) (4)	

In deciding what data to include in the labeling, consideration was given to the intended target audience. In this case, in addition to the prescriber, there will be many stakeholders interested in understanding the potential effects of the abuse-deterrent changes to the formulation of OxyContin on the different routes of abuse. Therefore, the study results have been provided in table format with median and mean values, as a figure representing the continuous responder function for drug liking, and as text describing key cutoff points (e.g. no reduction, some reduction, 30% reduction, and 50% reduction in drug liking) in the responder analysis.

The following table represents the final agreed-upon language for the package insert.

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