CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272

OTHER REVIEW(S)

MEMORANDUM: DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 08-MAR-2010

TO: N 22272 File for OxyContin® (oxycodone hydrochloride controlled-release) Tablets

FROM: Craig M. Bertha, Ph.D.
Chemistry Reviewer
ONDQA, Division I, Branch II

THROUGH: Prasad Peri, Ph.D.
Acting Branch Chief
ONDQA, Division I, Branch II

SUBJECT: Review of CMC-related labeling revisions in the 24-FEB-2010, amendment of N22272

BACKGROUND: After review of the 04-FEB-2010, labeling amendment to N22272, the CMC team sent two comments to the applicant regarding the labeling. The 24-FEB-2010, amendment is a response to these comments and is the subject of this review.

EVALUATION:

Agency Comment 1
Revise the DESCRIPTION section of the labeling to state that the new OxyContin formulations (b) (4) .

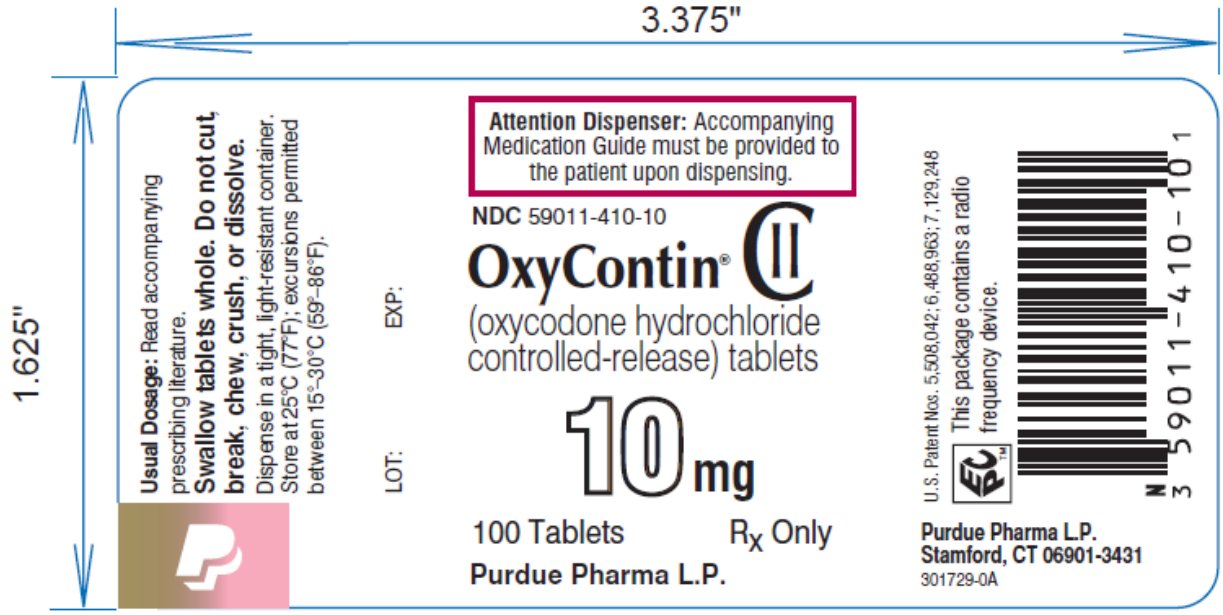
Summary of Applicant Response
The applicant has chosen the alternative and has removed the statement from the DESCRIPTION section altogether.

Evaluation: Adequate.

Agency Comment 2
For each strength of the drug product, revise and resubmit the mock-ups of the bottle labels such that it is clear where the lot number and expiration date will be located. Although the location had been clear in earlier versions of the bottle labels, it is not clear in the latest version supplied with the February 4, 2010, amendment.

Summary of Applicant Response

The location of the lot number and the expiration date are now clear on the labels. The label for the 10 mg strength is reproduced below as an example to illustrate the placement.



Evaluation: Adequate.

Recommendation

NAI. The CMC team has no further comments on the labels/labeling.

_____

Craig M. Bertha, Ph.D.
Chemistry Reviewer

cc:
Orig. NDA 22-272
C.Bertha/ONDQA//Reviewer/3/8/10
PPeri/ONDQA/Acting Branch Chief_____
DChristodoulou/ONDQA/PAL
LBasham/DAARP/Regulatory PM

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22272	ORIG-1	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/

CRAIG M BERTHA
03/08/2010

PRASAD PERI
03/08/2010
I concur

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:	September 29, 2009
To:	Bob Rappaport, MD, Director Division of Anesthesia, Analgesia and Rheumatology Products
Through:	Kristina C. Arnwine, PharmD, Team Leader Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Loretta Holmes, BSN, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Container Label Review
Drug Name:	OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg
Application Type/Number:	NDA 22-272
Applicant:	Purdue Pharma L.P.
OSE RCM #:	2009-717

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