CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-272Orig1s014

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

FDA CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF ANESTHESIA, ANALGESIA, AND ADDICTION PRODUCTS
HFD-170, Building 22, 10903 New Hampshire Ave. Silver Spring MD 20993
Tel:(301)796-2280

Memo to File

TO: **NDA 22-272**

DATE: **April 16, 2013**

FROM: **Sharon Hertz, M.D.**
Deputy Director, DAAAP

RE: **Research Triangle Institute OxyContin Surveillance Data**

Several agency memoranda regarding reformulated OxyContin (OCR) refer to surveillance conducted by the Research Triangle Institute (RTI). RTI surveyed trends in the abuse of OxyContin before and after OCR was introduced into the market. RTI used two data sources: (1) the Client Treatment Study (CTS); and (2) the National Survey of Drug Use and Health (NSDUH).

These data, referred to collectively as the "RTI data," were reviewed by FDA. An executive summary of the results was submitted to a public docket (FDA-2013P-0045). FDA considered the RTI data in making the relisting determination for original OxyContin (OC). However, FDA did not rely on the RTI data (nor was it necessary) to approve Supplement 014 to Purdue's NDA 22-272.

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/s/

SHARON H HERTZ
04/16/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022272/S-014

ACKNOWLEDGEMENT --
PRIOR APPROVAL SUPPLEMENT

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

Attention: Beth Connelly
Associate Director, Regulatory Affairs

Dear Ms. Connelly:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER:	022272
SUPPLEMENT NUMBER:	S-014
PRODUCT NAME:	OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets
DATE OF SUBMISSION:	September 12, 2012
DATE OF RECEIPT:	September 14, 2012

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 DEPENDENDCE** section, (b) (4)

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 13, 2012, in accordance with 21 CFR 314.101(a).

If the application is filed, the goal date will be March 14, 2013.

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3).

SUBMISSION REQUIREMENTS

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia,
and Addiction Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, call me at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Lisa E. Basham, M.S.
Senior Regulatory Health Project Manager
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

LISA E BASHAM
09/25/2012