

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA #: NDA 022-272

Drug Name: OxyContin (oxycodone hydrochloride) tablet

Indication(s): Management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate

Applicant: Purdue Pharma L.P.

Date(s): Letter date: December 10, 2014, PDUFA date: June 8, 2015

Review Priority: Priority

Biometrics Division: II

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Keywords: NDA review, Pediatric Written Request (PWR), Clinical Studies

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