CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022272Orig1s027

<u>STATISTICAL REVIEW(S)</u>

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
Statistical Reviewer:	Feng Li, Ph.D.
Concurring Reviewers:	Freda Cooner, Ph.D.
Medical Division:	Division of Anesthesia, Analgesia, and Addiction Products
Clinical Team:	Javier Muniz, M.D.
Project Manager:	Diana Walker
Keywords:	NDA review, Pediatric Written Request (PWR), Clinical Studies

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