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APPLICATION NUMBER:
201655Orig1s000

PHARMACOLOGY REVIEW(S)

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

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number: 201-655
Supporting document/s: 000
Applicant's letter date: Submit date: July 7, 2010
CDER stamp date: Received date: July 7, 2010
Product: Oxymorphone HCl (b)(4) Extended-Release Tablet
Indication: Relief of moderate to severe pain in patients requiring continuous opioid therapy for an extended period of time
Applicant: Endo Pharmaceuticals
Review Division: Division of Anesthesia and Analgesia Products
Reviewer: Elizabeth A. Bolan, Ph.D.
Supervisor/Team Leader: R. Daniel Mellon, Ph.D.
Division Director: Bob Rappaport, M.D.
Project Manager: Lisa Basham

Template Version: December 7, 2009

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