CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204592Orig1s000

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

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA #:	NDA 204-592
Drug Name:	Zorvolex (diclofenac acid)
Indication(s):	Treatment of mild to moderate acute pain
Applicant:	Iroko Pharmaceuticals, LLC
Date(s):	Letter date: December 21, 2012, PDUFA date: October 20 , 2013
Review Priority:	Standard
Biometrics Division:	II
Statistical Reviewer:	Feng Li, Ph.D.
Concurring Reviewers:	Janice Derr, Ph.D.
Medical Division:	Division of Anesthesia, Analgesia, and Addiction Products
Clinical Team:	Steven Galati, M.D.
Project Manager:	Swati Patwardhan, Ph.D.
Keywords:	NDA review, Clinical Studies

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