

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**204592Orig1s000**

**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 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

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**Keywords:** NDA review, Clinical Studies

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