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RESEARCH**

*APPLICATION NUMBER:*

**208082Orig1s000**

**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 Number:** 208,082

**Drug Name:** Austedo (deutetrabenazine) (b) (4) Tablet

**Indication:** Treatment of Chorea Associated with Huntington's Disease

**Applicant:** Teva Pharmaceuticals, Inc.

**Dates:** Receipt Date: May 29, 2015  
PDUFA Goal Date: May 29, 2016

**Review Priority:** Standard

**Biometrics Division:** Division of Biometrics I

**Statistical Reviewer:** Xiangmin Zhang, Ph.D.

**Concurring Reviewers:** Kun Jin, Ph.D., Team Leader  
Hsien Ming Hung, Ph.D., Director

**Medical Division:** Division of Neurology Products

**Clinical Team:** Kenneth Bergmann, M.D., Clinical Reviewer  
Gerald Podskalny, D.O., Team Leader  
Eric Bastings, M.D., Deputy Director  
William Dunn, M.D., Director

**Project Manager:** Stacy Metz, Pharm.D.

**Keywords:** analysis of covariance, clinical studies, mixed models, NDA review

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