CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208082Orig1s000

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

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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