CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203284Orig1s000

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

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA #:	NDA 203-284
Supplement #:	
Drug Name:	RAVICTI^{TM} (glycerol phenylbutyrate; HPN-100); TID, in liquid solution, orally with meals
Indication(s):	Adjunctive therapy for chronic management of adults and pediatric patients ≥ 6 years of age with urea cycle disorders (UCDs)
Applicant:	Hyperion Therapeutics, Inc.
Date(s):	Stamp Date: December 23, 2011
	PDUFA Goal date: January 23, 2013
Review Priority:	Standard with Major Amendment (13 month review cycle)
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Behrang Vali M.S.
Concurring Reviewers:	Mike Welch Ph.D.
Medical Division:	Division of Gastroenterology and Inborn Errors Products
Clinical Team:	MO: Nancy Snow, M.D.
	MOTL and CDTL: Melanie Blank, M.D.
Project Manager:	Jessica Benjamin M.P.H.

Keywords: NDA review, Clinical Studies, Active Control/Non-Inferiority

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