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APPLICATION NUMBER:

203284Orig1s000

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 203-284

Supplement #:

Drug Name: RAVICTI™ (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)

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

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