CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203565Orig1s000

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/BLA Serial Number:	NDA 203565/0
Drug Name:	Ferric Carboxymaltose
Indication(s):	Iron Deficiency Anemia
Applicant:	Luitpold Pharmaceuticals, Inc.
Date(s):	Stamp Date: 10/3/2011
	PUDFA Date: August 3, 2012
Review Priority:	Standard
Biometrics Division:	Division of Biometrics V
Statistical Reviewer:	Kyung Yul Lee, Ph.D., Statistical Reviewer
Concurring Reviewers:	Mark Rothmann, Ph.D., Lead Mathematical Statistician
	Tomas Gwise, Ph.D., Division Deputy Director
Medical Division:	Division of Hematology Products
Clinical Team:	Dr. Min Lu, Clinical Reviewer
	Dr. Kathy Robie Suh, Clinical Team Leader
Project Manager:	Ms. Baird

Keywords:

Iron deficiency anemia, impaired renal function, hemoglobin, noninferiority test, ANCOVA,

Table of Contents

LIST OF TABLES

LIST OF FIGURES

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