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APPLICATION NUMBER:

208551Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA	208551, SDN 1
Submission Date(s)	June 25, 2015
Brand Name	TRIFERIC
Generic Name	Ferric pyrophosphate citrate
Reviewer	Olanrewaju Okusanya, Pharm.D, MS
Team Leader	Gene Williams, Ph.D
OCP Division	DCP V
OND Division	DHP
Sponsor	Rockwell Medical Inc.
Relevant IND(s)	51290
Submission Type; Code	Original-1 (Type 3- New Dosage Form)
Formulation; Strength(s)	Powder for dissolution; 272 mg Fe/ packet
Indication	The replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD)

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Reference ID: 3904534

1 EXECUTIVE SUMMARY

TRIFERIC (Ferric pyrophosphate citrate) is a mixed ligand iron complex in which iron (III) is bound to citrate and pyrophosphate. TRIFERIC was approved for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). The approved dosage form was single-use ampules each containing 27.2 mg of iron (III) per 5mL. One ampule is added to 2.5 gallons of liquid bicarbonate and delivers 27.2 mg of iron per every 2.5 gallons of liquid bicarbonate concentrate, to deliver a final hemodialysate concentration of 2 µM (110 µg/L) of iron. The current submission is for a new packaging that will provide Triferic as an API powder in a packet for dilution. No clinical pharmacology information was included in this application, and no changes to clinical pharmacology related portions of the package insert are proposed. The applicant cross-referenced their previously approved application NDA 206317.

1.1 Recommendation

The application is approvable from a clinical pharmacology perspective.

1.2 Post-marketing Requirements and Commitments

No post-marketing requirements or commitments are recommended.

1.3 Summary of Important Clinical Pharmacology and Biopharmaceutics Findings

No clinical pharmacology information was included in this application, and no changes to clinical pharmacology related portions of the package insert are proposed. There are no clinical pharmacology and biopharmaceutics findings.

Signatures

Olanrewaju O. Okusanya, Pharm.D., MS Clinical Pharmacology Reviewer Division of Clinical Pharmacology V	Gene Williams, Ph.D. Team Leader Division of Clinical Pharmacology V

Cc: DHP: CSO – **K Scott;** MTL – **K. Robie-Suh**; MO – **M Lu**
DCP V: Reviewer - **O Okusanya**, TL – **G Williams**, DDD – **B Booth;** DD – **A Rahman**

2 QUESTION BASED REVIEW

No QBR was conducted. The Applicant cross-referenced their previously-approved NDA 206317.

3 DETAILED LABELING RECOMMENDATIONS

No changes to clinical pharmacology related portions of the package insert were proposed by the applicant. The reviewer has no labeling recommendations.

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/s/

OLANREWAJU OKUSANYA
03/18/2016

GENE M WILLIAMS
03/18/2016
I concur with the recommendations