CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208551Orig1s000

PHARMACOLOGY REVIEW(S)

MEMORANDUM

TO: File for NDA 208551

FROM: Pedro L. Del Valle, PhD
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology
Office of Hematology and Oncology Products

THROUGH: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology
Office of Hematology and Oncology Products

DATE: April 11, 2016

SUBJECT: Recommend Approval of NDA

TRIFERIC® (ferric pyrophosphate citrate) solution was approved on January 23, 2015 under NDA 206317 for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDDCKD).

Rockwell Medical Inc. submitted a new NDA on June 25, 2015 for Triferic powder (b) (4) packets. This new dosage form, containing 272 mg iron(III) per packet for addition to 25 gallons of bicarbonate concentrate is for the same indication as approved for NDA 206317.

No new clinical data or nonclinical data was submitted with this application. The iron concentration in the final dialysate delivered to patients is the same as in the original NDA approval. The only material difference betwee (b) (4) powder packet and the packaging materials. The relevant nonclinical and clinical information are contained in NDA 206317. Rockwell Medical Inc. cross referenced the annotated PI to the relevant sections of NDA 206317 and NDA 208551. The PI was edited for conversion to the PLLR format and the Applicant submitted final comments on the proposed USPI on March 22, 2016. No further edits to section 8 were necessary.

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/s/

PEDRO L DEL VALLE
04/11/2016

CHRISTOPHER M SHETH
04/11/2016