

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

212860Orig1s000

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 MEMO

Clinical Studies

NDA #: NDA 212860
Supplement #: S000
Drug Name: Triferic (b) (4) (Ferric Pyrophosphate Citrate)
Indication(s): For the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).
Applicant: Rockwell Medical, Inc.
Receipt Date: May 28, 2019
PDUFA Date: March 28, 2020
Completion Date: July 18, 2019
Review Priority: Standard
Biometrics Division: Division of Biometrics V
Statistical Reviewer: Haiyan Chen
Concurring Reviewers: Yu-te Wu, TL
Rajeshwari Sridhara, Division Director
Medical Division: Oncology and Hematology Product
Clinical Team: Andrew Dmytrijuk, Medical Reviewer
Kathy Robie-Suh, Team Leader
Project Manager: Kristopher Kolibab
Keywords: Triferic (b) (4) Triferic-solution, hemodialysis-dependent chronic kidney disease (HDD-CKD), efficacy, statistical review

Memo to be filed:

The original Triferic ® (Ferric Pyrophosphate Citrate) solution is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). This submission is to seek approval of the new IV form. Triferic^{(b) (4)} package is intended to be administered directly into the pre-dialyzer or post-dialyzer blood line for use in patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). Reference is made to NDA206317 for statistical review of the efficacy aspect of Triferic based on the Triferic solution. Since there is no additional clinical data submitted, no statistical review was conducted for this submission. This statistical review memo documents the fact that no statistical review is necessary.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

HAIYAN N CHEN
07/18/2019 03:48:44 PM

YU-TE WU
07/18/2019 05:59:38 PM

RAJESHWARI SRIDHARA
07/19/2019 11:06:30 AM