

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208551Orig1s000**

**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 208551  
**Supplement #:** S000  
**Drug Name:** Triferic ® (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:** June 25, 2015  
**PDUFA Date:** April 25, 2016  
**Completion Date:**  
**Review Priority:** Standard

**Biometrics Division:** Division of Biometrics V  
**Statistical Reviewer:** Yuan-Li Shen  
**Concurring Reviewers:** Rajeshwari Sridhara

**Medical Division:** Oncology and Hematology Product  
**Clinical Team:** Min Lu, Medical Reviewer  
Kathy Robie-Suh, Team Leader  
**Project Manager:** Scott Kimberly

**Keywords:**

[http://intranetapps.fda.gov/scripts/ob\\_apps/ob/eWork/uploads/eWork/2009/Keywords-in-DFS.htm](http://intranetapps.fda.gov/scripts/ob_apps/ob/eWork/uploads/eWork/2009/Keywords-in-DFS.htm)

**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 powder form which contains the same iron concentration in the final hemodialysate provided by Triferic Solution. Triferic powder package is intended to be used in dialysis center to prepare master batches of dialysate 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 older 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.

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/s/  
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YUAN L SHEN  
04/22/2016

RAJESHWARI SRIDHARA  
04/25/2016