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RESEARCH**

*APPLICATION NUMBER:*

**212860Orig1s000**

**NON-CLINICAL REVIEW(S)**

## MEMORANDUM

TO: File for NDA 212860

FROM: Pedro L. Del Valle, PhD, Fellow ATS  
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THROUGH: Christopher Sheth, PhD  
Pharmacology-Toxicology Supervisor  
Division of Hematology Oncology Toxicology  
Office of Hematology and Oncology Products

DATE: July 26, 2019

SUBJECT: Nonclinical Filing and Review for NDA 212860

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This New Drug Application for Triferic<sup>(b) (4)</sup> includes a new dosage form containing 6.5 mg iron (III) per 4.5 ampule for intravenous infusion. This new dosage form is for the same indication as NDA 206317 and NDA 208551:

“Triferic is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).”

The Applicant cross-referenced all nonclinical data to NDA 206317. There are no outstanding issues from a nonclinical perspective for filing/review nor comments for the proposed USPI.

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/s/  
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PEDRO L DELVALLE  
07/26/2019 05:53:47 AM

CHRISTOPHER M SHETH  
07/26/2019 07:30:47 AM