



NDA 206317/S-012

## **SUPPLEMENT APPROVAL**

Rockwell Medical Inc  
Attention: Raymond Pratt, MD  
Chief Medical Officer  
30142 S Wixom Rd  
Wixom, MI 48393

Dear Dr. Pratt:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 10, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Triferic (ferric pyrophosphate citrate) Solution, 5.44 mg Iron (III)/mL.

This “Changes Being Effected” supplemental new drug application provides for changes to the principal display panel of the container label for Triferic (ferric pyrophosphate citrate) solution 5 mL ampules.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 206317/S-012.**” Approval of this submission by FDA is not required before the labeling is used.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Chief, Branch I  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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