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RESEARCH**

APPLICATION NUMBER:

206317Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Memorandum

Date: June 24, 2014

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Drug Name and Strength: Triferic (soluble ferric pyrophosphate) Injection
27.2 mg Iron per 5 mL (5.44 mg FE/mL)

Application Type/Number: NDA 206317

Applicant/sponsor: Rockwell Medical

OSE RCM #: 2014-17175

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Triferic, under NDA 206317. DMEPA previously found the name Triferic, acceptable for this product in OSE Review# 2013-422 dated July 23, 2013 under IND 051290. We note that there is a change in the product strength [from (b) (4) mg Iron per 5 mL (b) (4) mg Iron per mL) to 27.2 mg Iron per 5 mL (5.44 mg Iron per mL)], for NDA 206317 currently under review. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessments of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database (see section 4) to identify names with high orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2013-422. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in product strength. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 16, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. The Division of Hematology Products (DHP) did not concur with OPDP's assessment and continue to express concerns that Triferic, implies "triple iron" (see OSE Review 2013-422, IND 051290, dated July 23, 2013). DMEPA does not find the use of "tri" to be misleading and concurs with OPDP's promotional assessment of the proprietary name.

3 CONCLUSIONS

We have completed our review of the proposed proprietary name, Triferic, and have concluded that this name is acceptable.

If you have further questions or need clarifications, please contact Kevin Wright, OSE Project Manager, at 301-796-3621.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Triferic, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 3, 2014 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. Wright K. Proprietary Name Review for Triferic (IND 051290). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 Jul 23. OSE RCM No.: 2013-422.
2. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
3. ***Phonetic and Orthographic Computer Analysis (POCA)***
POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

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06/24/2014

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