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RESEARCH**

APPLICATION NUMBER:

212595Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 12, 2019
Application Type and Number:	NDA 212595
Product Name and Strength:	Riomet ER (metformin hydrochloride) extended release oral suspension, 500 mg per 5 mL (100 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharmaceutical Industries (Sun Pharma)
Panorama #:	2019-29181453
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Riomet ER, which was found conditionally acceptable under IND 127945 on December 17, 2018.^a We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Riomet ER would not misbrand the proposed product per their March 1, 2019 email. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Riomet ER.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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.

Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The February 13, 2019 search of USAN stems determined that the proposed proprietary name, Riomet ER, contains the United States Adopted Name (USAN) stem “-io-” in the infix position used by the USAN Council to indicate iodine-containing contrast media, as documented in our prior name review.^a We maintain our non-objection to the use of the two-letter USAN stem “io,” incorporated into the proposed proprietary name, Riomet ER.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via email on March 8, 2019. At that time, we also requested additional information or concerns that could inform our review. Per email correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on March 11, 2019, they stated no additional concerns with the proposed proprietary name, Riomet ER.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Riomet ER, is acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

^a Rimmel S. Proprietary Name Review for Riomet ER (IND 127945). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Dec 17. Panorama No.: 2018-24252508.

3.1 COMMENTS TO SUN PHARMACEUTICAL INDUSTRIES (SUN PHARMA)

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

If any of the proposed product characteristics as stated in your submission, received on February 7, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

- 1. USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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/

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03/12/2019 03:16:06 PM

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03/15/2019 12:16:22 PM