CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210942Orig1s000

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:	June 7, 2018
Application Type and Number:	NDA 210942
Product Name and Strength:	Gloperba (colchicine) solution, 0.12 mg/mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Romeg Therapeutics, LLC
Panorama #:	2018- 22138158
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Gloperba, which was found conditionally acceptable under IND 129187 on February 16, 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 the proposed name would not misbrand the proposed product. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

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 name contains any USAN stems as of the last USAN updates. The May 1, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on May 23, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on May 31, 2018, they stated no additional concerns with the proposed proprietary name, Gloperba.

3 CONCLUSIONS

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 is acceptable.

If you have any questions or need clarifications, please contact Saharat Patanavanich, OSE project manager, at 240-402-0139.

3.1 COMMENTS TO THE APPLICANT

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

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[a] [McMillan, T]. Proprietary Name Review for Gloperba (IND 129187). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); [2018 FEB 16]. Panorama No. [2017-17369646].

If any of the proposed product characteristics as stated in your submission, received on April 5, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. **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.

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/s/

TERESA S MCMILLAN
06/07/2018

SARAH K VEE
06/07/2018