CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212819Orig1s000

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:	April 9, 2019
Application Type and Number:	NDA 212819
Product Name and Strength:	Recarbrio (imipenem, cilastatin, and relebactam) for injection, 500 mg/500 mg/250 mg per vial
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp.
Panorama #:	2019-28842235
DMEPA Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Recarbrio, which was found conditionally acceptable under IND 108754 on May 11, 2018.[a]

We note that in the January 23, 2019 Request for Proprietary Name Review submission the proposed product strength is listed as 500 mg imipenem, 500 mg cilastatin, 250 mg relebactam, which is consistent with the strength provided, as well as assessed, in our previous review of the proposed proprietary name Recarbrio under IND 108754.[c] However, the strength on the proposed container label submitted on November 16, 2018, as part of the original NDA submission, includes the strength represented as "1.25 g per vial." The Office of Pharmaceutical Quality (OPQ) is currently working to determine the appropriate strength for this product.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Recarbrio would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment for Recarbrio.

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. We also evaluated previously identified names taking into account the possible change in strength (b) (4) to 1.25 g, as well as the possible dosing (b) (4) to 1.25 grams every 6 hours. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Recarbrio.

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 January 25, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Recarbrio.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to DAIP via e-mail on April 3, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAIP on April 9, 2019, they stated no additional concerns with the proposed proprietary name, Recarbrio.

[a] Myers, D. Proprietary Name Review for Recarbrio (IND 108754). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAY 11. Panorama No.: 2017-19173629.

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, Recarbrio, is acceptable.

If you have any questions or need clarifications, please contact Nicholas Miles, OSE project manager, at 301-796-7025.

3.1 COMMENTS TO MERCK SHARP & DOHME CORP.

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

If any of the proposed product characteristics as stated in your submission, received on January 23, 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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