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RESEARCH**

APPLICATION NUMBER:

212614Orig1s000

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 13, 2019
Application Type and Number: NDA 212614
Product Name and Strength: Trijardy XR (empagliflozin, linagliptin, and metformin extended release) tablet, 25 mg/5 mg/1,000 mg, 12.5 mg/2.5 mg/1,000 mg, 10 mg/5 mg/1,000 mg, 5 mg/2.5 mg/1,000 mg
Product Type: Multiple Ingredient Product
Rx or OTC: Prescription (Rx)
Applicant/Sponsor Name: Boehringer Ingelheim Pharmaceuticals, Inc. (BI)
Panorama #: 2019-30480044
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, Trijardy XR, which was found conditionally acceptable under IND 122138 on February 13, 2019.^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 Trijardy XR would not misbrand the proposed product per their April 16, 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 Trijardy XR.

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 April 9, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Trijardy XR.

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 June 5, 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 June 11, 2019, they stated no additional concerns with the proposed proprietary name, Trijardy XR.

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, Trijardy XR, is acceptable.

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

3.1 COMMENTS TO BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

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

^a Conrad A. Proprietary Name Review for Trijardy XR (IND 122138). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Feb 13. Panorama No.: 2018-25623360.

If any of the proposed product characteristics as stated in your submission, received on April 1, 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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06/13/2019 03:47:25 PM

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06/17/2019 08:32:19 AM