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APPLICATION NUMBER:

207620Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW 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 11, 2015
Application Type and Number: NDA 207620
Product Name and Strength: Entresto (sacubitril/valsartan) Tablets, 24 mg/26 mg, 49 mg/51 mg, 97 mg/103 mg
Product Type: Multi-Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Novartis Pharmaceuticals Corporation
Submission Date: April 24, 2015
Panorama #: 2015-47393-1
DMEPA Primary Reviewer: Janine Stewart, PharmD
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Entresto, which was previously found acceptable in OSE Review #2014-25640, dated November 17, 2014 under IND 104628¹; and in OSE Review #2015-47393, dated January 28, 2015 under NDA 207620.² We note that there is [REDACTED] (b) (4) [REDACTED] 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg) since our last review. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2014-25640. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in strength, dose, and frequency. 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 May 22, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Entresto, is acceptable from both a promotional and safety perspective under NDA 207620.

If you have further questions or need clarifications, please contact Darrell Lyons, OSE Project Manager, at 301-796-4092.

¹ Gao T. Proprietary Name Review for Entresto (IND 104628). 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); 20141117. 36 p. OSE RCM No.: 2014-25640.

² Stewart J. Proprietary Name Review Memo for Entresto (NDA 207620). 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); 20150128. 2 p. OSE RCM No.: 2015-47393.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 24, 2015 submission are altered, the name must be resubmitted for review. If you have further questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

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.

2. **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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