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RESEARCH**

APPLICATION NUMBER:

209139Orig1s000

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 23, 2017
Application Type and Number:	NDA 209139
Product Name and Strength:	Prexxartan (Valsartan) Oral Solution, 4 mg/mL
Product Type:	Single ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Carmel Biosciences, Inc.
Submission Date:	December 30, 2016
Panorama #:	2017-12759163
DMEPA Primary Reviewer:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Prexxartan under NDA 209139, which was found acceptable under IND 119968¹. We note that there are changes in the proposed indication of use, dose and frequency, and how supplied characteristics for NDA 209139 (See Table 1). All other product characteristics remain the same.

Table 1. Comparison between IND and NDA

	IND 119968	NDA 209139
Proposed Indication of use	Lower blood pressure and improve blood flow	Adult Hypertension (HTN), Pediatric HTN, Heart Failure, and Post-myocardial Infarction
Proposed Dose and Frequency	80 mg/day to 320 mg/day given in dosing intervals of (b) (4) 2 times daily	Adult HTN: 80 mg to 320 mg once daily Pediatric HTN: (b) (4) (up to 160 mg total) Heart Failure: 40 mg to 160 mg twice daily Post-myocardial Infarction: 20 mg to 160 mg twice daily
How Supplied	20 mL unit dose, and 16 ounce HDPE bottle	20 mL unit dose, 120 mL bottle, and 473 mL (16 ounce) bottle

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 Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern in our previous review¹, 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 change in the proposed indication of use, dose and frequency, and how supplied characteristics for NDA 209139. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 3, 2017 search of USAN stems did not find any

¹ Thomas, S. Proprietary Name Review for Prexxartan (IND 119968). 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); 2016 October 26. 28 pgs. OSE RCM No.: 2016-8856967.

USAN stems in the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Prexxartan, is acceptable from both a promotional and safety perspective under the NDA 209139.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 30, 2016 submission are altered, 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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SARAH E THOMAS

03/23/2017

DANIELLE M HARRIS on behalf of CHI-MING TU

03/23/2017