

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209296Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	February 6, 2017
<b>Application Type and Number:</b>	NDA 209296
<b>Product Name and Strength:</b>	Cinvanti (aprepitant) Emulsion for Injection 130 mg per vial
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Heron Therapeutics, Inc
<b>Panorama #:</b>	2017-12504235
<b>DMEPA Primary Reviewer:</b>	Matthew Barlow, RN, BSN
<b>DMEPA Team Leader:</b>	Mishale Mistry, PharmD, MPH

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Cinvanti, which was found conditionally acceptable under IND 125926 on December 13, 2016.<sup>a</sup> 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 Division of Gastroenterology & Inborn Error Products (DGIEP) 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 January 31, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## **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 Nicholas Miles, OSE project manager, at 301-796-7025.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your January 17, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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<sup>a</sup> Barlow, M. Proprietary Name Review for Cinvanti (IND 125926). 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 DEC 13. Panorama No. 2016-8803457

#### 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/  
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MATTHEW J BARLOW  
02/06/2017

MISHALE P MISTRY  
02/08/2017