

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**210303Orig1s000**

**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>	December 11, 2017
<b>Application Type and Number:</b>	NDA 210303
<b>Product Name and Strength:</b>	Zemdri (plazomicin) for injection, 50 mg/mL
<b>Total Product Strength:</b>	500 mg/10 mL
<b>Product Type:</b>	Single-Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Achaogen, Inc.
<b>Panorama #:</b>	2017-18652866
<b>DMEPA Safety Evaluator:</b>	Deborah Myers, RPh, MBA
<b>DMEPA Team Leader:</b>	Otto L. Townsend, PharmD

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Zemdri, which was found conditionally acceptable under IND 102563 on June 13, 2017.<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 Anti-Infective Products (DAIP) 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 November 15, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

### **2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW**

DMEPA communicated our findings to the Division of Anti-Infective Products (DAIP) via e-mail on December 8, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on December 11, 2017, they stated no additional concerns with the proposed proprietary name, Zemdri.

## **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 Janet Higgins, OSE project manager, at 204-402-0330.

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

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

If any of the proposed product characteristics as stated in your October 25, 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> Myers, D. Proprietary Name Review for Zemdri (IND 102563). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JUN 13. Panorama No. 2017-12915039.

#### **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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DEBORAH E MYERS  
12/11/2017

OTTO L TOWNSEND  
12/11/2017