

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**213969Orig1s000**

**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>	July 28, 2020
<b>Application Type and Number:</b>	NDA 213969
<b>Product Name and Strength:</b>	Zokinvy (lonafarnib) capsules, 50 mg and 75 mg
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Prescription (Rx)
<b>Applicant/Sponsor Name:</b>	Eiger BioPharmaceuticals, Inc. (Eiger)
<b>Panorama #:</b>	2020-39818575
<b>DMEPA Safety Evaluator:</b>	Sherly Abraham, R.Ph.
<b>DMEPA Team Leader:</b>	Idalia E. Rychlik, Pharm.D.

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Zokinvy, which was found conditionally acceptable under IND 139923 on April 15, 2020.<sup>a</sup> Thus, Eiger submitted the name, Zokinvy, under NDA 213969 for review on May 8, 2020. 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 Zokinvy would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Rare Diseases and Medical Genetics (DRDMG) concurred with the findings of OPDP's assessment for Zokinvy.

### **2.2 SAFETY ASSESSMENT**

For re-assessment of the proposed proprietary name, we 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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The July 21, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Zokinvy.

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

We communicated our findings to the Division of Rare Diseases and Medical Genetics (DRDMG) via e-mail on July 24, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Rare Diseases and Medical Genetics (DRDMG) on July 28, 2020, they stated no additional concerns with the proposed proprietary name, Zokinvy.

## **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, Zokinvy, is acceptable.

If you have any questions or need clarifications, please contact Su-Lin Sun, OSE project manager, at 301-796-0036

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<sup>a</sup>Mishale M. and Owens, L. Proprietary Name Review for Zokinvy (139923). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 15. Panorama No.: 2019-35371946

### **3.1 COMMENTS TO EIGER BIOPHARMACEUTICALS, INC.**

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

If any of the proposed product characteristics as stated in your submission, received on May 8, 2020, 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.

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/s/  
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