CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216873Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	July 29, 2022
Application Type and Number:	NDA 216873
Product Name and Strength:	Ojjaara (momelotinib) tablet, 100 mg, 150 mg, and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sierra Oncology, Inc. (Sierra)
PNR ID #:	2022-1044724629
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Deputy Director (Acting):	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ojjaara, which was found conditionally acceptable under IND 101155 on January 5, 2022.[a] Thus, Sierra submitted the name, Ojjaara, under NDA 216873 for review on June 16, 2022. 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 Ojjaara would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Ojjaara. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Ojjaara.

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 1, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Ojjaara.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On July 29, 2022, we communicated our determination to the Division of Non-Malignant Hematology (DNH).

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, Ojjaara, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO SIERRA ONCOLOGY, INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 16, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Karpow, C. Proprietary Name Review for Ojjaara (IND 101155). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 JAN 05. PNR ID No. 2021-1044724078.

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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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