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RESEARCH**

APPLICATION NUMBER:

211349Orig1s000

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:	June 14, 2018
Application Type and Number:	NDA 211349
Product Name and Strength:	Xospata (gilteritinib) tablets, 40 mg
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Astellas
Panorama #:	2018-21936799
DMEPA Safety Evaluator:	Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Xospata, which was found conditionally acceptable under IND 117548 on December 5, 2017.^a 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 Hematology Products (DHP) 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 April 24, 2018 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 Hematology Products (DHP) via e-mail on June 11, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on June 14, 2018, they stated no additional concerns with the proposed proprietary name, Xospata.

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 Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on March 29, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

^a Garrison, N. Proprietary Name Review for Xospata (gilteritinib) IND 117548. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 05. Panorama No. 2017-15630949.

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/

CASMIR I OGBONNA
06/15/2018

HINA S MEHTA
06/15/2018