CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212306Orig1s000

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:	November 14, 2018
Application Type and Number:	NDA 212306
Product Name and Strength:	Xpovio (selinexor) tablet, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Karyopharm Therapeutics
Panorama #:	2018-25819016
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Xpovio, which was found conditionally acceptable under IND 114042 on July 17, 2018.[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 Xpovio would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment for Xpovio.

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 proposed proprietary name contains any USAN stems as of the last USAN updates. The October 4, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Xpovio.

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 November 13, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products (DHP) on November 13, 2018, they stated no additional concerns with the proposed proprietary name, Xpovio.

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, Xpovio, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 301-796-4845.

3.1 COMMENTS TO KARYOPHARM THERAPEUTICS

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

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[a] Ogbonna, C. Proprietary Name Review for Xpovio (IND 114042). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Jul 17. Panorama No.: 2017-20817087

REFERENCES

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/

MAXIMILIAN STRAKA
11/14/2018

HINA S MEHTA
11/15/2018