CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210875Orig1s000

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:	April 28, 2020
Application Type and Number:	NDA 210875
Product Name and Strength:	Kynmobi (b) (4) sublingual film, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sunovion Pharmaceuticals Inc (Sunovion)
Panorama #:	2020-39055498
DMEPA Primary Reviewer:	Justine Kalonia, PharmD
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Kynmobi, which was found unacceptable under NDA 210875 on July 24, 2019 and February 18, 2020.[ab] The proposed proprietary name, Kynmobi, was found to be vulnerable to medication errors due to confusion with another product, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Kynmobi, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 210875 is May 21, 2019, whereas the underlying application for (b) (4) status. Therefore, if the proposed proprietary name, Kynmobi, is granted approval under NDA 210875 on or before May 21, 2019, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***.

Thus, Sunovion resubmitted the proposed proprietary name, Kynmobi, for review on April 2, 2020.

2 METHODS AND DISCUSSION

2.1 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 9, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4)***, and determined that if NDA 210875 for Kynmobi is approved on or before the May 21, 2019, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)*** given the underlying application for (b) (4)*** (b) (4) status.

Based upon our safety assessment of the proposed proprietary name, Kynmobi, the application goal date for NDA 210875, and the status of the underlying application for (b) (4)***, we find Kynmobi conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Division of Neurology 1 (DN 1) via e-mail on April 21, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 1 (DN 1)

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[a] Owens, L. Proprietary Name Review Memo for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUL 24. Panorama No. 2018-22076836-1.

[b] Morris, C. Proprietary Name Review for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 FEB 18. Panorama No. 2019-35948893.

on April 28, 2020, they stated no additional concerns with the proposed proprietary name, Kynmobi.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Kynmobi, is acceptable.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO SUNOVION PHARMACEUTICALS INC

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

If any of the proposed product characteristics as stated in your submission, received on April 2, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

1. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

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