CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217469Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	September 9, 2022
Application Type and Number:	NDA 217469
Product Name and Strength:	Vevye (cyclosporine) ophthalmic solution, 0.1% (1 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novaliq GmbH (Novaliq)
PNR ID #:	2022-1044724706
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD., BCPS.
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD., MPH.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vevye, which was found conditionally acceptable under IND 128163 on August 18, 2022.[a] Novaliq submitted the name, Vevye, under NDA 217469 for review on August 10, 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 Vevye would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Vevye. The Division of Ophthalmology (DO) concurred with the findings of OPDP's assessment for Vevye.

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 September 2, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Vevye.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On September 9, 2022, we communicated our determination to the Division of Ophthalmology (DO).

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, Vevye, is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

3.1 COMMENTS TO NOVALIQ GMBH

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

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[a] Getahun, S. Proprietary Name Review for Vevye (IND 128163). Silver Spring (MD): FDA, CDER, OSE, DMEPA1 (US); 2022 AUG 18. PNR ID No. 2022-1044724452.

If any of the proposed product characteristics as stated in your submission, received on August 10, 2022, 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.

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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09/09/2022 04:16:27 PM

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