CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214028Orig1s000

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 23, 2021
Application Type and Number:	NDA 214028
Product Name and Strength:	Vuity (pilocarpine hydrochloride) ophthalmic solution, 1.25%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AbbVie Inc. (AbbVie)
PNR ID #:	2021-1044723846
DMEPA Safety Evaluator:	Sofanit Getahun, PharmD. BCPS.
DMEPA Team Leader:	Valerie S. Vaughan, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vuity, which was found conditionally acceptable under IND 122483 on January 11, 2021.[a] Thus, AbbVie submitted the name, Vuity, under NDA 214028 for review on March 2, 2021. 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 Vuity would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Ophthalmology (DO) concurred with the findings of OPDP's assessment for Vuity.

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 April 5, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Vuity.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Ophthalmology (DO). At that time we also requested additional information or concerns that could inform our review. On April 22, 2021, the Division of Ophthalmology (DO) stated no additional concerns with the proposed proprietary name, Vuity.

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, Vuity, is acceptable.

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

[a] Getahun, S. Proprietary Name Review for Vuity (IND 122483). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JAN 11. Panorama No.: 2020-42375055.

3.1 COMMENTS TO ABBVIE INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 2, 2021, 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/

SOFANIT N GETAHUN
04/23/2021 10:58:57 AM

VALERIE S VAUGHAN
04/23/2021 11:04:20 AM