CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209905Orig1s000

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 18, 2018
Application Type and Number:	NDA 209905
Product Name and Strength:	Evekeo ODT (amphetamine sulfate) Orally Disintegrating Tablets 5 mg, 10 mg, 15 mg, 20 mg, (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Arbor Pharmaceuticals, LLC
Panorama #:	2018-22112224
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Evekeo ODT, which was found conditionally acceptable under IND 124019 on September 20, 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 Psychiatry Products (DPP) 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 May 16, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Additionally, provided that the Office of Pharmaceutical Quality (OPQ) determines that the product meets the criteria/standards for an orally disintegrating tablet, we continue to find the modifier "ODT" acceptable for this product.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on May 21, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on May 31, 2018, they stated they have no objections to the name provided the product meets the definition of an orally disintegrating tablet.

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 Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO THE APPLICANT

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

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[a] Holmes, L. Proprietary Name Review for Evekeo ODT (IND 124019). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Sep 20. Panorama No. 2017-14744672.

If any of the proposed product characteristics as stated in your submission, received on April 3, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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/

LORETTA HOLMES
06/18/2018

LOLITA G WHITE
06/18/2018