CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209229Orig1s000

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:	December 12, 2017
Application Type and Number:	NDA 209229
Product Name and Strength:	Lucemyra (lofexidine HCl), 0.18 mg tablet
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	US WorldMeds, LLC
Panorama #:	2017-17766134
DMEPA Safety Evaluator:	James Schlick, MBA, RPh
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Lucemyra, which was found conditionally acceptable under IND 47857[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 Anesthesia, Analgesia, and Addiction Products (DAAAP) 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 September 29, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on December 8, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on December 11, 2017, they stated no additional concerns with the proposed proprietary name, Lucemyra.

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 Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO THE APPLICANT

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

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[a] Roosta, N. Proprietary Name Review for Lucemyra IND 47857. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JUL 26. Panorama No.2017-13576754.

If any of the proposed product characteristics as stated in your September 26, 2017 submission 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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES H SCHLICK
12/12/2017

OTTO L TOWNSEND
12/12/2017