

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**203324Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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**Date of This Review:** January 29, 2016  
**Application Type and Number:** NDA 203324  
**Product Name and Strength:** Photrexa (Riboflavin) Ophthalmic Solution, 0.12%  
Photrexa (Riboflavin with 20% Dextran), Ophthalmic Solution, 0.12%  
**Product Type:** Single Ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Avedro, Inc.  
**Panorama #:** 2015-1997223 and 2015-1997475  
**DMEPA Primary Reviewer:** Michelle Rutledge, PharmD  
**DMEPA Team Leader:** Yelena Maslov, PharmD

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## **1 INTRODUCTION**

This memorandum is to re-assess the proposed proprietary names, Photrexa and Photrexa Viscous under NDA 203324, which were found acceptable in a previous OSE review# 2014-40632 and 2014-40633, NDA 203324<sup>1</sup>. We note that there is no change in product characteristics since our last review.

## **2 METHODS AND DISCUSSION**

To re-assess the proposed proprietary name, the Division of Medication Error Prevention and Analysis (DMEPA), conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2014-40632 and 2014-40633. Additionally, 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 evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 27, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## **3 CONCLUSIONS**

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have any questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your November 16, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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<sup>1</sup> Kapoor R. Proprietary Name Review for Photrexa and Photrexa Viscous (NDA 203324). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Jan 13. 42 p. OSE RCM NO.: 2014-40632 and 2014-40633.

#### 4 REFERENCES

1. Kapoor R. Proprietary Name Review for Photrexa and Photrexa Viscous (NDA 203324). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Jan 13. 42 p. OSE RCM NO.: 2014-40632 and 2014-40633.
2. *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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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MICHELLE K RUTLEDGE  
01/29/2016

LUBNA A MERCHANT on behalf of YELENA L MASLOV  
01/29/2016