CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212640Orig1s000

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:	March 19, 2019
Application Type and Number:	NDA 212640
Product Name and Strength:	Exservan (riluzole) oral film, 50 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Aquestive Therapeutics
Panorama #:	2019-29064942
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Exservan, which was found conditionally acceptable under IND 130939 on October 1, 2018.[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 Exservan would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment for Exservan.

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 proposed proprietary name contains any USAN stems as of the last USAN updates. The February 11, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Exservan.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on March 11, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on March 18, 2019, they stated no additional concerns with the proposed proprietary name, Exservan.

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, Exservan, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

[a] Rider, B. Proprietary Name Review for Exservan (IND 130939). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 OCT 01. Panorama No.: 2018-22237515.

3.1 COMMENTS TO AQUESTIVE THERAPEUTICS

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

If any of the proposed product characteristics as stated in your submission, received on January 31, 2019, 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.

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