CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212640Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
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)

Date of This Memorandum:	October 31, 2019
Requesting Office or Division:	Division of Neurology Products (DNP)
Application Type and Number:	NDA 212640
Product Name and Strength:	Exservan (riluzole) oral film, 50 mg
Applicant/Sponsor Name:	Aquestive Therapeutics
OSE RCM #:	2019-339-3
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader (Acting):	Briana Rider, PharmD, CPPS

1 PURPOSE OF MEMORANDUM

Aquestive Therapeutics submitted revised carton labeling on October 25, 2019 for Exservan in response to a recommendation developed upon internal discussion with The Office of Prescription Drug Promotion (OPDP). We concurred with OPDP to recommend Aquestive add the statement "Do not administer with liquids" after the statement "Keep in place until film dissolves" under the "How to Use" section on the carton labeling.[a] The Division of Neurology Products (DNP) requested that we review the revised carton labeling for Exservan (Appendix A).

2 CONCLUSION

Aquestive implemented the recommendation, and we have no additional recommendations at this time.

[a] Recommendation submitted to Aquestive Therapeutics via email on October 23, 2019. Email available at: \\cdsesub1\evsprod\nda212640\0011\m1\us\112-other-corr\request-for-information-additional-labeling-comments.pdf

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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/

JOHN C MORRIS
10/31/2019 09:12:30 AM

BRIANA B RIDER
10/31/2019 09:16:59 AM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	October 23, 2019
To:	William Dunn, MD Director **Division of Neurology Products (DNP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Sharon W. Williams, MSN, BSN, RN Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Sapna Shah, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Instructions for Use
Drug Name (established name):	EXSERVAN (riluzole)
Dosage Form and Route:	oral film
Application Type/Number:	NDA 212640
Applicant:	Aquestive Therapeutics

1 INTRODUCTION

On January 31, 2019, Aquestive Therapeutics. submitted for the Agency's review an Orignal New Drug Application (NDA) for EXSERVAN (riluzole) oral film. The purpose of the submission is to seek approval for marketing EXSERVAN (riluzole) for the treatment of amyotrophic lateral sclerosis (ALS).

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Neurology Products (DNP) on April 3, 2019 for DMPP and OPDP respectively to review the Applicant's proposed IFU for EXSERVAN.

2 MATERIAL REVIEWED

- Draft EXSERVAN (riluzole) IFU received on January 31, 2019, and received by DMPP and OPDP on October 17, 2019.
- Draft EXSERVAN (riluzole) use Prescribing Information (PI) received on January 31, 2019, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on October 17, 2019.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additonally, in 2008, the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the IFU we:

- simplified wording and clarified concepts where possible
- ensured that the IFU is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the IFU is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the IFU meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The IFU is acceptable with our recommended changes.

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