CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217639Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	October 4, 2022
Application Type and Number:	NDA 217639
Product Name and Strength:	Orserdu (elacestrant) tablet, (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Stemline Therapeutics, Inc. (Stemline)
PNR ID #:	2022-1044724670
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

(b) (4)

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Orserdu, which was found conditionally acceptable under IND 124748 on April 4, 2022.[b] Thus, Stemline submitted the name, Orserdu, under NDA 217639 for review on July 15, 2022. 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 Orserdu would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Orserdu. The Division of Oncology 1 (DO1) concurred with OPDP's assessment for Orserdu.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, 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 reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 16, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Orserdu.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On October 4, 2022, we communicated our determination to the Division of Oncology 1 (DO1).

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, Orserdu, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO STEMLINE THERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on July 15, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[b] Gao, Tingting. Proprietary Name Review for Orserdu (IND 124748). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 APR 04. PNR ID No. 2021-1044724232

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.

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/

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10/04/2022 04:41:45 PM

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10/05/2022 08:51:27 AM

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