

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214103Orig1s000

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:	June 25, 2020
Application Type and Number:	NDA 214103
Product Name and Strength:	Oxlumo (lumasiran) injection, 94.5 mg/0.5 mL
Total Product Strength:	94.5 mg/0.5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Alnylam Pharmaceuticals, Inc (Alnylam)
Panorama #:	2020-38950204
DMEPA Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Oxlumo, which was found conditionally acceptable under IND 128941 on August 8, 2019.^a

Thus, Alnylam submitted the name, Oxlumo, under NDA 214103 for re-review on April 3, 2020. Alnylam clarified that the proposed strength remains unchanged since our last review as, 94.5 mg/0.5 mL.^b 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 Oxlumo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Oxlumo.

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. Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 17, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Oxlumo.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Cardiology and Nephrology (DCN) via e-mail on June 17, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiology and Nephrology (DCN) on June 24, 2020, they stated no additional concerns with the proposed proprietary name, Oxlumo.

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, Oxlumo, is acceptable.

^a Thomas, S. Proprietary Name Review for Oxlumo (IND 128941). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Aug 8. Panorama No.: 2019-32308034.

^b Alnylam Pharmaceuticals, Inc. Response to FDA Information Request. Cambridge (MA): Alnylam Pharmaceuticals, Inc. 2020 JUN 12. Available from: [\\cdsesub1\evsprod\nda214103\0014\m1\us\111-information-amendment\response-to-proprietary-name-review-ir-received-on-29may2020.pdf](https://cdsesub1/evsprod/nda214103/0014/m1/us/111-information-amendment/response-to-proprietary-name-review-ir-received-on-29may2020.pdf)

If you have any questions or need clarifications, please contact Wana Manisitpitskul, OSE project manager, at (240) 402-4156.

3.1 COMMENTS TO ALNYLAM PHARMACEUTICALS, INC

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

If any of the proposed product characteristics as stated in your submission, received on April 3, 2020, 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.

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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06/25/2020 10:27:16 AM

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