CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215515Orig1s000

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 23, 2021
Application Type and Number:	NDA 215515
Product Name and Strength:	Amvuttra (vutrisiran) Injection, 25 mg/0.5 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Alnylam Pharmaceuticals Inc. (Alnylam)
PNR ID #:	2021-1044723922
DMEPA Safety Evaluator:	Justine Kalonia, PharmD
DMEPA Acting Team Leader:	Celeste Karpow, PharmD, MPH
DMEPA Deputy Director:	Danielle Harris, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Amvuttra, which was found conditionally acceptable under IND 139086 on March 19, 2021.[a] Thus, Alnylam submitted the name, Amvuttra, under NDA 215515 for review on April 14, 2021. 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 Amvuttra would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Amvuttra.

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 May 4, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Amvuttra.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Neurology 1 (DN 1). At that time we also requested additional information or concerns that could inform our review. On June 22, 2021, the Division of Neurology 1 (DN 1) stated no additional concerns with the proposed proprietary name, Amvuttra.

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, Amvuttra, is acceptable.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO ALNYLAM PHARMACEUTICALS INC.

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

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[a] Baugh, D. Proprietary Name Review for Amvuttra (IND 139086). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 19. Panorama No.: 2020-1043051292.

If any of the proposed product characteristics as stated in your submission, received on April 14, 2021, 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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