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RESEARCH**

APPLICATION NUMBER:

218614Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 3, 2024
Application Type and Number:	NDA 218614
Product Name, Dosage Form, and Strength:	Tryngolza (olezarsen) injection, 80 mg/0.8 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Ionis Pharmaceuticals Inc. (Ionis)
PNR ID #:	2024-1044725741
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tryngolza, which was found conditionally acceptable under IND 136692 on March 08, 2024.^a

Thus, Ionis submitted the proposed proprietary name, Tryngolza, under NDA 218614 for re-review on April 19, 2024.^b We note that there is a change in (b) (4) to a single (b) (4) (80 mg/0.8 mL) for NDA 218614. All other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tryngolza would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Tryngolza. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not comment on the findings of OPDP's assessment for Tryngolza.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Tryngolza, 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. We also evaluated previously identified names taking into account the change in (b) (4) to a (b) (4) product (80 mg/0.8 mL). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Tryngolza.

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 May 21, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tryngolza.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On June 3, 2024, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

^a Patel, V. Proprietary Name Review for Tryngolza (IND 136692). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 08. PNR ID No. 2023-1044725338.

^b Request for Proprietary Name Review NDA 218614 Tryngolza. Carlsbad (CA): Ionis Pharmaceuticals Inc.; 2024 Apr 19. Available from: <\\CDSESUB1\EVSPROD\nda218614\0001\m1\us\118-proprietary-names\proprietary-name-request.pdf>.

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, Tryngolza, is conditionally acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO IONIS PHARMACEUTICALS INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 19, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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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