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RESEARCH**

APPLICATION NUMBER:

219491Orig1s000

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 4, 2025
Application Type and Number:	NDA 219491
Product Name, Dosage Form, and Strength:	Nuzolvence (zoliflodacin) granules for oral suspension, 3 grams
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Entasis Therapeutics, Inc. (ETI)
PNR ID #:	2025-1044726400
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nuzolvence, which was found conditionally acceptable under IND 118958 on March 11, 2025.^a Thus, ETI submitted the proposed proprietary name, Nuzolvence, under NDA 219491 for re-review on April 15, 2025, and subsequent amendment received on April 23, 2025.^b We note that all product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nuzolvence 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 Nuzolvence. The Division of Anti-Infectives (DAI) concurred with the findings of OPDP's assessment for Nuzolvence.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Nuzolvence, 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 April 18, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name, Nuzolvence.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On June 4, 2025, DMEPA 1 communicated our determination to the Division of Anti-Infectives (DAI).

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, Nuzolvence, is conditionally acceptable.

^a Myers, D. Proprietary Name Review for Nuzolvence (IND 118958). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 MAR 11. PNR ID No. 2024-1044726016.

^b Amendment to Request for Proprietary Name Review for Nuzolvence NDA 219491. Waltham (MA): Entasis Therapeutics, Inc.; 2025 APR 23. Available from: <\\CDSESUB1\EVSPROD\nda219491\0002\m1\us\118-prop-names\proprietary-names.pdf>.

3.1 COMMENTS TO ENTASIS THERAPEUTICS, INC.

We have completed our review of the proposed proprietary name, Nuzolvence, 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 15, 2025, 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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