

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761142Orig1s000

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:	August 26, 2019
Application Type and Number:	BLA 761142
Product Name and Strength:	Uplizna (inebilizumab-xxxx ^a) injection, 10 mg/mL
Total Product Strength:	100 mg/10 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Viela Bio
Panorama #:	2019-32766656
DMEPA Safety Evaluator:	Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader (Acting):	Briana Rider, PharmD

^a The proper name for Uplizna has not yet been determined; therefore, “inebilizumab-xxxx” is used in this review as the proper name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Uplizna, which was found conditionally acceptable under IND 117295 on June 12, 2019.^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 Uplizna would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment for Uplizna.

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 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 August 20, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Uplizna.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Neurology Products (DNP) via e-mail on August 26, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on August 26, 2019, they stated no additional concerns with the proposed proprietary name, Uplizna.

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, Uplizna, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO VIELA BIO

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

^b Baugh, D. Proprietary Name Review for Uplizna (IND 117295). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jun 12. Panorama No.: 2018-28117528.

If any of the proposed product characteristics as stated in your submission, received on June 27, 2019, 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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08/26/2019 05:51:12 PM

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08/26/2019 07:41:28 PM