CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761235Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	11/2/2021
Responsible OND Division:	Division of Ophthalmology (DO)
Application Type and Number:	IND 119225 BLA 761235
Product Name and Strength:	Vabysmo (faricimab-svoa) injection 6 mg/0.05 mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Genentech Inc. (Genentech)
FDA Received Date:	January 25, 2021 (IND) May 28, 2021 (BLA)
Nexus NPNS ID #:	2021-1 (IND) 2021-41 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Irene Z. Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Genentech for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761235.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On January 25, 2021 (IND) and May 28, 2021 (BLA), Genentech submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Genentech also provided findings from an external study conducted by (b) (4), evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Genentech:

Table 1. Suffixes submitted by Genentech***

1.	(b) (4)
2.	svoa
3.	(b) (4)
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for Review of Proposed Suffixes BLA 761235. South San Francisco (CA): Genentech, Inc..; 2021 May 28. Available from: \\CDSESUB1\evsprod\bla761235\0001\m1\us\request-review-suffixes.pdf

(b) (4)

We reviewed Genentech's proposed suffixes in the order of preference listed by Genentech, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 (b) (4)

(b) (4)

2.2 faricimab-svoa

Genentech's second proposed suffix, -svoa, is comprised of 4 distinct letters.

We determined that the proposed suffix -svoa, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On October 19, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Ophthalmology (DO) on November 2, 2021.

4 CONCLUSION

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

We find Genentech's proposed suffix -svoa acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to faricimab-svoa. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Genentech Inc.

We find the nonproprietary name, faricimab-svoa, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, faricimab-svoa will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our finding.

We also note that the first proposed suffix is unacceptable for the following reason:

1. (b) (4)

(b) (4)

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/s/

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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:	August 23, 2021
Application Type and Number:	BLA 761235
Product Name and Strength:	Vabysmo (faricimab-xxxx)[a] injection, 6 mg/0.05 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
PNR ID #:	2021-1044724002
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD. BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Division Director (Acting):	Irene Z. Chan PharmD. BCPS

[a] A nonproprietary name suffix has not been designated; therefore, -xxxx is used throughout the review as a placeholder.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vabysmo, which was found conditionally acceptable under IND 119225 on April 5, 2021.[b] Thus, Genentech submitted the name, Vabysmo, under BLA 761235 for review on May 28, 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 Vabysmo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Ophthalmology (DO) concurred with the findings of OPDP's assessment for Vabysmo.

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 June 16, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Vabysmo.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Ophthalmology (DO). At that time, we also requested additional information or concerns that could inform our review. On August 23, 2021, the Division of Ophthalmology (DO) stated no additional concerns with the proposed proprietary name, Vabysmo.

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, Vabysmo, is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

[b] Getahun, S. Proprietary Name Review for Vabysmo (IND 119225). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 APR 05. Panorama No.: 2020-43367716.

3.1 COMMENTS TO GENENTECH, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 28, 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.

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/s/

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