CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761371Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	7/18/2024
Responsible OND Division:	Division of Neurology 2 (DN 2)
Application Type and Number:	IND 100593 BLA 761371
Product Name and Strength:	Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) injection 920 mg and 23,000 units/23 mL (40 mg and 1,000 units/mL)
Product Type:	Multiple Ingredient Product
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
FDA Received Date:	April 12, 2023(IND) November 13, 2023 (BLA)
Nexus NPNS ID #:	2023-216 (IND) 2023-213 (BLA)
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

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 761371.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On April 12, 2023 (IND) and November 13, 2023 (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)[a], 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.	ocsq
3.	(b) (4)
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for Nonproprietary Name Suffix BLA 761371. San Francisco (CA): Genentech, Inc.; 2023 Nov 13. Available from: \\CDSESUB1\EVSPROD\bla761371\0001\m1\us\proprietary-name.pdf

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 ocrelizumab and hyaluronidase (b) (4)

Genentech's first proposed suffix (b) (4)

(b) (4)

2.2 ocrelizumab and hyaluronidase-ocsq

Genentech's second proposed suffix, -ocsq, is comprised of 4 distinct letters. We note that the letters 'sq' within the suffix represent the medical abbreviation for 'subcutaneously'. We considered whether the inclusion of the letters 'sc' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -ocsq, 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 2 ANALYSIS

These findings were shared with OPDP. On July 11, 2024, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Neurology 2 (DN 2) on July 18, 2024.

4 CONCLUSION

We find Genentech's proposed suffix -ocsq acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to ocrelizumab and hyaluronidase-ocsq. DMEPA 2 will communicate our findings to the Applicant via letter.

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[a] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4.1 Recommendations for Genentech, Inc.

We find the nonproprietary name, ocrelizumab and hyaluronidase-ocsq, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, ocrelizumab and hyaluronidase-ocsq 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 findings.

We also note that the first proposed suffixes are unacceptable for the following reasons:

1. ocrelizumab and hyaluronidase (b) (4)

(b) (4)

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/s/

CARLOS M MENA-GRILLASCA
07/18/2024 08:15:10 AM

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07/18/2024 09:22:37 AM

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	February 6, 2024
Application Type and Number:	BLA 761371
Product Name and Strength:	Ocrevus Zunovo (ocrelizumab and hyaluronidase-xxxx[a]) injection, 920 mg and 23,000 units/23 mL (40 mg and 1,000 units/mL)
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
PNR ID #:	2023-1044725472
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Acting Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

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

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ocrevus Zunovo, which was found conditionally acceptable under IND 100593 on April 20, 2023.[b] Genentech submitted the name, Ocrevus Zunovo, under BLA 761371 for review on November 17, 2023. 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 Ocrevus Zunovo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Ocrevus Zunovo.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we considered our previous analysis of the use of the same root name, Ocrevus, whether the use of a modifier is sufficient to distinguish the products, and whether the use of the modifier, Zunovo, is appropriate 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 previous conclusion and we agree with the previous analysis of the proposed proprietary name, Ocrevus Zunovo. 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 December 14, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Ocrevus Zunovo.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On February 6, 2024, we communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

Our re-assessment did not identify any concerns that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Ocrevus Zunovo, is conditionally acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

[b] Morris, C. Proprietary Name Review for Ocrevus Zunovo (IND 100593). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2023 APR 20. PNR ID No. 2023-1044724971.

3.1 COMMENTS TO GENENTECH, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 17, 2023, 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/

JOHN C MORRIS
02/06/2024 05:04:17 PM

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