CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761244Orig1s000

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)

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Date of This Review:	3/11/2022
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761244
Product Name and Strength:	Spevigo (spesolimab-sbzo) injection 450 mg/7.5 mL (60 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals, Inc. (BI)
FDA Received Date:	October 1, 2021
Nexus NPNS ID #:	2021-56
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 BI for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761244.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 1, 2021, BI submitted a list of 8 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. BI also provided their own evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by BI:

Table 1. Suffixes submitted by BI***

(b) (4)

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

[a] Request for Review of Suffixes for Proper Name. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2021 Oct 01. Available from: \\CDSESUB1\evsprod\bla761244\0001\m1\us\spesolimab-suffix-submission-report.pdf

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

2.1 spesolimab (b) (4)

BI's first proposed suffix, (b) (4), is comprised of 4 distinct letters. We note that all the letters that comprise the suffix (b) (4) are contained within the proposed proprietary name (b) (4), and three of the letters appear in the suffix in the same order in which they appear in the proposed name (b) (4) Therefore, we find that (b) (4) in the context of this product, implies the proposed proprietary name 'Spevigo'. Thus, we find the proposed suffix, (b) (4), is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Name of Biological Product guidance[a].

We acknowledge that our evaluation differs from that submitted by the applicant. However, the applicant's evaluation did not evaluate the suffix connotation of the applicant's proposed proprietary name, Spevigo.

2.2 spesolimab-sbzo

BI's second proposed suffix, -sbzo, is comprised of 4 distinct letters.

We determined that the proposed suffix -sbzo, 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 March 9, 2022, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on March 11, 2022.

4 CONCLUSION

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

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[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

4.1 Recommendations for Boehringer Ingelheim Pharmaceuticals, Inc.

We find the nonproprietary name, spesolimab-sbzo, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, spesolimab-sbzo 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. spesolimab (b) (4)

We find your first proposed suffix, (b) (4), unacceptable. We note that all the letters that comprise the suffix (b) (4) are contained within the proposed proprietary name (b) (4), and three of the letters appear in the suffix in the same order in which they appear in the proposed name (b) (4) Therefore, we find that (b) (4) in the context of this product, implies the proposed proprietary name 'Spevigo'. Thus, we find the proposed suffix, (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Name of Biological Product guidance[a].

We acknowledge that our evaluation differs from the evaluation that you submitted. However, you did not evaluate the potential suffix connotation of your proposed proprietary name, Spevigo.

[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

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/s/

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03/11/2022 07:15:12 PM

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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:	November 23, 2021
Application Type and Number:	BLA 761244
Product Name and Strength:	Spevigo (spesolimab-xxxx)[a] injection, solution, 450 mg/7.5 mg (60 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals Inc (Boehringer)
PNR ID #:	2021-1044724213
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "spesolimab-xxxx" throughout this review in place of the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Spevigo, which was found conditionally acceptable under IND 131311 on June 23, 2021.[b] Thus, Boehringer submitted the name, Spevigo, under BLA 761244 for review on October 1, 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 Spevigo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Spevigo.

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 November 2, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Spevigo.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Dermatology and Dentistry (DDD). At that time, we also requested additional information or concerns that could inform our review. On November 18, 2021, the Division of Dermatology and Dentistry (DDD) stated no additional concerns with the proposed proprietary name, Spevigo.

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, Spevigo, is acceptable.

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO BOEHRINGER INGELHEIM PHARMACEUTICALS INC

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

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[b] Patel, M. Proprietary Name Review for Spevigo (IND 131311). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 23. PNR ID No. 2021-1044723842.

If any of the proposed product characteristics as stated in your submission, received on October 1, 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.

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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11/23/2021 04:43:28 PM

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