

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761099Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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:	March 27, 2019
Responsible OND Division:	Division of Oncology Products 2 (DOP2)
Application Type and Number:	BLA 761099
Product Name and Strength:	Zirabev (bevacizumab-bvzr) Injection, 25 mg/mL
Total Product Strength:	100 mg/4 mL and 400 mg/16 mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Pfizer, Inc. (Pfizer)
FDA Received Date:	June 29, 2018
OSE RCM #:	2018-1732
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Pfizer for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761099.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 29, 2018, Pfizer submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Pfizer also provided findings from an external study conducted by (b) (4) (b) (4)^b, evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Pfizer:

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

We reviewed Pfizer's proposed suffixes in order of preference listed by Pfizer, along with the supporting data they submitted, using the principles described in the applicable guidance.^c

2.1 bevacizumab- (b) (4)

(b) (4)

^a Request for Review of Nonproprietary Name for BLA 761099. New York (NY): Pfizer, Inc.; 2018 JUN 29. Available from: <\\cdsesub1\evsprod\bla761099\0003\m1\us\req-nonproprietary-name.pdf>

^b Proposed Suffixes for BLA 761099 (b) (4) 2018 JUNE 29. Available from: <\\cdsesub1\evsprod\bla761099\0003\m1\us\proposed-suffixes.pdf>

^c 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>

2.2 bevacizumab-bvzr

Pfizer's second proposed suffix, -bvzr, is comprised of four distinct letters.

We determined that the proposed suffix -bvzr, 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'S ANALYSIS

These findings were shared with OPDP, TBBS, ORP, and OCC. In email correspondence dated March 6, 2019, OPDP concurred with DMEPA's assessment and conclusion. DMEPA also communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on March 27, 2019.

4 CONCLUSION

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

4.1 Recommendations for Pfizer, Inc.

We find the nonproprietary name, bevacizumab-bvzr, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, bevacizumab-bvzr 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 would inform you of our finding.

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

1. bevacizumab- (b) (4)

We find your proposed suffix, - (b) (4) unacceptable. The proposed suffix, - (b) (4) contains

(b) (4)

Thus, we find the proposed suffix - (b) (4) inconsistent with the principles described in the Nonproprietary Naming of Biological Product guidance^a.

We acknowledge that our evaluation differs from that of the external study that you submitted, performed by the (b) (4) (b) (4). However, the external study did not evaluate the potential suffix (b) (4)

(b) (4)

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

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/

CARLOS M MENA-GRILLASCA
03/27/2019 01:23:12 PM

LUBNA A MERCHANT on behalf of DANIELLE M HARRIS
03/27/2019 01:29:43 PM

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:	December 10, 2018
Application Type and Number:	BLA 761099
Product Name and Strength:	Zirabev (bevacizumab-xxxx) ^a Injection, 25 mg/mL
Total Product Strength:	100 mg/4 mL and 400 mg/16 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer, Inc.
Panorama #:	2018-26371062
DMEPA Safety Evaluator:	Colleen Little, PharmD
Acting DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

^a Zirabev has been developed as a proposed biosimilar to US-licensed Avastin (bevacizumab). Since the proper name for Zirabev has not yet been determined, “bevacizumab-xxxx” is used throughout this review as the proper name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Zirabev, which was found conditionally acceptable under IND 117038 on September 18, 2018.^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 Zirabev would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's assessment for Zirabev.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 13, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Zirabev.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on November 29, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 2 (DOP2) on December 7, 2018, they stated no additional concerns with the proposed proprietary name, Zirabev.

3 CONCLUSIONS

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, Zirabev, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO PFIZER, INC.

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

^b Little, C. Proprietary Name Review for Zirabev (IND 117038). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 SEP 18. Panorama No.: 2018-21991488.

If any of the proposed product characteristics as stated in your submission, received on October 3, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

- 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/

COLLEEN L LITTLE
12/10/2018

SEVAN H KOLEJIAN
12/10/2018