

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761078Orig1s000

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:	March 2, 2017
Application Type and Number:	BLA 761078
Product Name and Strength:	Bavencio (avelumab) Injection, 20 mg/mL
Total Product Strength:	200 mg/10 mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	EMD Serono, Inc
Panorama #:	2017-12586177
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to assess the proposed proprietary name, Bavencio, for BLA 761078. The proprietary name Bavencio was found conditionally acceptable under IND 119394^a and BLA 761049^b.

We note that there is a change in the proposed indication for BLA 761078. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For 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. We also evaluated previously identified names taking into account the change in indication (see Table 1). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The February 8, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

	IND 119394 and BLA 761049	BLA 761078
Indication of Use	<p>BAVENCIO is indicated for the treatment of patients with metastatic Merkel cell carcinoma (MCC).</p> <p>This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.</p>	<p>BAVENCIO is indicated for the treatment of patients with locally advanced or metastatic urothelial cancer (UC) with disease progression on or after platinum-based therapy.</p> <p>This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.</p>

^a Thomas, S. Proprietary Name Review for Bavencio (IND 119394). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 APR 21. Panorama No. 2016-2751083.

^b Thomas, S. Proprietary Name Review for Bavencio (BLA 761049). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 OCT 26. Panorama No. 2016-9761719.

3 CONCLUSIONS

Our assessment did not identify any names that represent a potential source of drug name confusion. Therefore, the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 17, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

- 1. USAN Stems (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)**
USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TINGTING N GAO
03/02/2017

CHI-MING TU
03/02/2017