

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761467Orig1,Orig2s000

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:	July 29, 2025
Responsible OND Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761467
Product Name and Strength:	Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmpl injection 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa/2 mL and 790 mg pembrolizumab and 9,600 units berahyaluronidase alfa/4.8 mL (165 mg pembrolizumab and 2,000 units berahyaluronidase alfa/mL)
Product Type:	Multiple Ingredient Product
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC (Merck)
FDA Received Date:	January 24, 2025
Nexus NPNS ID #:	2025-300
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 Merck for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761467.

2 Assessment of the Nonproprietary Name

On January 24, 2025, Merck submitted a list of 5 suffixes, in their order of preference, to be used in the nonproprietary name of their product.^a Table 1 presents the list of suffixes submitted by Merck:

Table 1

Suffixes submitted by Merck	
1.	(b) (4)
2.	pmpH
3.	(b) (4)
4.	(b) (4)
5.	(b) (4)

We reviewed Merck's proposed suffixes in the order of preference listed by Merck, using the principles described in the applicable guidance.

2.1 pembrolizumab and berahyaluronidase alfa- (b) (4)

Merck's first proposed suffix, (b) (4)

We note that the letters (b) (4) We considered whether the inclusion of the letters (b) (4) within the suffix could be 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 also note that the letters (b) (4). When considered in its entirety, the suffix as proposed, (b) (4) may (b) (4) thus, not be devoid of meaning.

Additionally, the proposed suffix (b) (4)

(b) (4) is too similar to another nonproprietary name suffix that was reviewed prior to the proposed nonproprietary name pembrolizumab and berahyaluronidase alfa- (b) (4) and that has been found to be conditionally acceptable for designation by FDA. Therefore, we find the proposed suffix (b) (4) inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix (which we conclude reasonably includes suffixes for products not yet licensed that are found conditionally acceptable).

^a Request for FDA Nonproprietary Name Suffix Review BLA 761467. Rahway (NJ): Merck Sharp & Dohme LLC; 2025 Jan 24. Available from: <\\CDSESUB1\EVSPROD\bla761467\0002\m1\us\multi-module-info-amendment-20250124.pdf>

2.2 pembrolizumab and berahyaluronidase alfa-pmph

Merck's second proposed suffix, -pmph, is comprise of 3 distinct letters (p, m, h).

We determined that the proposed suffix -pmph, is not too similar to any other product's 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 23, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 2 (DO2) on July 29, 2025.

4 Conclusion

We find Merck's proposed suffix -pmph acceptable. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Merck Sharp & Dohme LLC

We find the nonproprietary name, pembrolizumab and berahyaluronidase alfa-pmph, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, pembrolizumab and berahyaluronidase alfa-pmph 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. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

We also note that the following proposed suffix is unacceptable for the following reason(s):

1. pembrolizumab and berahyaluronidase alfa- (b) (4)

The proposed suffix, (b) (4) is too similar to another nonproprietary name suffix that has been found conditionally acceptable for designation to a biological product that is under review by FDA. We find the proposed suffix, (b) (4) is therefore inconsistent with the principle outlined in the Nonproprietary Naming of Biological Products Guidance that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix (which we conclude reasonably includes previously reviewed suffixes for products not yet licensed that are found conditionally acceptable).

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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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:	March 26, 2025
Application Type and Number:	BLA 761467
Product Name, Dosage Form, and Strength:	Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-xxxx) ^a injection, 395 mg and 4,800 units/2.4 mL (165 mg and 2,000 units/mL) and 790 mg and 9,600 units/4.8 mL (165 mg and 2,000 units/mL)
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp and Dohme LLC (Merck & Co.)
PNR ID #:	2025-1044726246
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

^a The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder pembrolizumab and berahyaluronidase alfa-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Keytruda Qlex, which was found conditionally acceptable under IND 161465 on November 6, 2024.^b Thus, Merck & Co. submitted the proposed proprietary name, Keytruda Qlex, under BLA 761467 for re-review on January 24, 2025.^c We note that all product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Keytruda Qlex would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Keytruda Qlex. The Division of Oncology 2 (DO2) concurred with the findings of OPDP's assessment for Keytruda Qlex.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Keytruda Qlex, 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 February 14, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name, Keytruda Qlex.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On March 26, 2025, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

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, Keytruda Qlex, is conditionally acceptable.

3.1 COMMENTS TO MERCK SHARP AND DOHME LLC

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

^b Mahmoud, S. Proprietary Name Review for Keytruda Qlex (IND 161465). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 NOV 06. PNR ID No. 2024-1044725801.

^c Request for proprietary and nonproprietary name review. BLA 761467: pembrolizumab and berahyaluronidase alfa (MK-3475A). Rahway (NJ): Merck Sharp and Dohme LLC; 2025 JAN 24. Available from:

<\\CDSESUB1\EVSPROD\bla761467\0002\m1\us\proprietary-names.pdf>.

If any of the proposed product characteristics as stated in your submission, received on January 24, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems>.

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/s/

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