CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761381Orig1s000
761429Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum

From:

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Biologics Suffix Specialist
Division of Medication Error Prevention and Analysys II
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Through:

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Gerald Dal Pan, MD, MHS
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Subject: Evaluation of the nonproprietary name for BLA 761429

Bristol Myers Squibb (BMS) submitted two Biologics License Applications (BLA 761381 and BLA 761429) pursuant to Section 351(a) of the Public Health Service Act. BLA 761381 for Opdivo Qvantig (nivolumab and hyaluronidase-xxxx) was submitted on February 29, 2024, to the Division of Oncology 3 (DO3) and the PDUFA goal date to take action on the application is December 29,

2024 (standard review). BLA 761429 for Opdivo Qvantig (nivolumab and hyaluronidase-xxxx) was submitted on March 29, 2024, to the DO3 and the PDUFA goal date to take action on the application is January 29, 2025 (standard review).

Per BMS, as agreed with the Agency during the Type B pre-BLA meeting (minutes dated March 5, 2024), the Type 9 BLA 761429 application will extensively cross-reference BLA 761381, including Module 3 Quality and Module 5 Clinical Study Reports. The drug substance (DS) and drug product (DP) in BLA 761429 is the same as the DS and DP in BLA 761381, and both BLAs propose a liquid formulation in single-dose vials with a single-strength presentation of 600 mg and 10,000 units/5 mL (120 mg and 2,000 Units/mL).

The proposed product is a combination of nivolumab, a programmed death receptor-1 (PD-1)-blocking antibody, and hyaluronidase, an endoglycosidase. Both BLAs propose the same formulation, in the same dosage form, strength, and same/overlapping dose, and route and frequency of administration and differ only in indication. See Appendix A – Product Characteristics Comparison Table for more information.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, stating the Agency's intention to designate proper names that include four-letter distinguishing suffixes for biological products.[a] Therefore, both of these 351(a) applications (BLA 761381 and BLA 761429) are within the scope of this naming guidance.

As such, the proposed nonproprietary name suffix -nvhy was found conditionally acceptable[b] for BLA 761381, and if approved the proper name designated in the license will be nivolumab and hyaluronidase-nvhy.

We carefully considered whether the nonproprietary name for BLA 761429 should include a different distinguishing suffix than that designated for BLA 761381 or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating the same proper name (i.e., nivolumab and hyaluronidase-nvhy) for BLA 761429. Among the factors we have considered are the following:

1. The drug substance (DS) and drug product (DP) in BLA 761429 are the same as the DS and DP in BLA 761381.

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[a] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "naming guidance").

[b] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761381 and IND 150904. Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Sep 06. Nexus NPNS ID. 2024-237 and 2023-212.

2. The formulation, dosage form, strength, dose, and route and frequency of administration are identical for BLA 761381 and BLA 761429. See Appendix A – Product Characteristics Comparison Table for more information.

3. Considering that BLA 761429 shares the same DS and DP as BLA 761381, no significant differences in immunogenicity profiles are expected.

3. BMS is proposing to use the same proprietary name (Opdivo Qvantig) for both of their nivolumab and hyaluronidase BLAs (BLA 761381 and BLA 761429) with a combined US Prescribing Information (USPI) for all indications. The naming convention of using the same proprietary name for different indications is not uncommon and has been found acceptable. DMEPA 2 found the proposed name Opdivo Qvantig conditionally acceptable for BLA 761381.[a]

4. Per BMS, as discussed in the Type B Pre-BLA meeting, BMS will not market their product for different indications under separate application numbers. As the original BLA 761381 is expected to be approved prior to BLA 761429 given the staggered nature of the submission of the BLAs, it is understood that FDA will "administratively close" BLA 761429 once approved (reclassified as a supplement) and therefore will only accept submissions to the "parent" BLA 761381.

As noted in the final Nonproprietary Naming of Biological Products guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a manufacturing lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. As noted above, the DS and DP in BLA 761429, nivolumab and hyaluronidase-xxxx, are the same as the DS and DP in BLA 761381. Also, as noted above, BMS is the applicant for BLA 761381 and BLA 761429.

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[a] Mahmoud, S. Proprietary Name Review for Opdivo Qvantig (BLA 761381). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 May 08. PNR ID No. 2024-1044725652.

Given the above factors, a different nonproprietary name for BLA 761429 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761429 could create confusion and would not further the goals of the naming convention.

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving the same nonproprietary name for BLA 761429.[a] We based this determination upon consideration of all the factors outlined above. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name format for this BLA.

The following will be communicated to BMS in an advice letter.

Comments for BMS for BLA 761429:

We have determined that nivolumab and hyaluronidase-nvhy will be the proper name designated in the license should your 351(a) BLA be approved during this review cycle. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review.

[a] See 21 C.F.R. § 10.115(d)(3) "Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence."

Appendix A - Product Characteristics Comparison Table

Proprietary Name	Opdivo Qvantig	Opdivo Qvantig
Application No.	BLA 761381	BLA 761429
Initial Approval/ PDUFA Goal	PDUFA goal date December 29, 2024	PDUFA goal date January 29, 2025
Active Ingredient	nivolumab and hyaluronidase-nvhy	nivolumab and hyaluronidase-xxxx
Indication	• Renal Cell Carcinoma (RCC) • Melanoma • Non-Small Cell Lung Cancer (NSCLC) • Squamous Cell Carcinoma of the Head and Neck (SCCHN) • Urothelial Carcinoma (UC) • Colorectal Cancer • Hepatocellular Carcinoma (HCC) • Esophageal Cancer • Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma	• Renal Cell Carcinoma (RCC) • Melanoma • Non-Small Cell Lung Cancer (NSCLC) • Squamous Cell Carcinoma of the Head and Neck (SCCHN) • Urothelial Carcinoma (UC) • Colorectal Cancer • Hepatocellular Carcinoma (HCC) • Esophageal Cancer • Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma NOTE: BLA 761429 is intended to support the following monotherapy/monotherapy maintenance/combination therapy (chemopherapy) indications: • Neoadjuvant and Adjuvant Treatment of Resectable Non-Small Cell Lung Cancer • Urothelial Carcinoma
Route of Administration	Subcutaneous	
Dosage Form	Injection	
Strength	600 mg and 10,000 Units/5 mL (120 mg and 2,000 Units/mL)	

Dose and Frequency	The recommended dosages of [TRADENAME] as a single agent are presented in Table 1.

Table 1: Recommended Dosages for [TRADENAME] as (b) (4)

Indication	Recommended [TRADENAME] Dosage	Duration of Therapy
Advanced renal cell carcinoma	600 mg nivolumab and 10,000 units hyaluronidase* every 2 weeks or 1,200 mg nivolumab and 20,000 units hyaluronidase* every 4 weeks	Until disease progression or unacceptable toxicity
Unresectable or metastatic melanoma		
Metastatic non-small cell lung cancer		
Squamous cell carcinoma of the head and neck		
Locally advanced or metastatic urothelial carcinoma		
Microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer		
Esophageal squamous cell carcinoma		
Adjuvant treatment of melanoma	600 mg nivolumab and 10,000 units hyaluronidase* every 2 weeks or 1,200 mg nivolumab and 20,000 units hyaluronidase* every 4 weeks	Until disease recurrence or unacceptable toxicity for up to 1 year
Adjuvant treatment of urothelial carcinoma		
Adjuvant treatment of resected esophageal or gastroesophageal junction cancer		

* Administer over approximately 3-5 minutes.

Table 2: Recommended Dosages for [TRADENAME] in Combination with Other Therapeutic Agents

Indication	Recommended [TRADENAME] Dosage	Duration of Therapy
Advanced renal cell carcinoma	600 mg nivolumab and 10,000 units hyaluronidase* every 2 weeks or 1,200 mg nivolumab and 20,000 units hyaluronidase* every 4 weeks Administer [TRADENAME] in combination with cabozantinib 40 mg orally once daily without food	[TRADENAME]: Until disease progression, unacceptable toxicity, or up to 2 years Cabozantinib: Until disease progression or unacceptable toxicity
	(b) (4)	
	(b) (4)	
Neoadjuvant treatment of resectable non-small cell lung cancer	900 mg nivolumab and 15,000 units hyaluronidase* with platinum-doublet chemotherapy on the same day every 3 weeks	In combination with platinum-doublet chemotherapy for 3 cycles
	(b) (4)	
Esophageal squamous cell carcinoma	600 mg nivolumab and 10,000 units hyaluronidase* every 2 weeks or 1,200 mg nivolumab and 20,000 units hyaluronidase* every 4 weeks Administer [TRADENAME] in combination with fluoropyrimidine- and platinum-containing chemotherapy	Until disease progression, unacceptable toxicity, or up to 2 years

How Supplied	single-dose vial
Storage	Store vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake.

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
11/18/2024 10:59:08 AM

MISHALE P MISTRY
11/18/2024 12:15:55 PM

GERALD J DALPAN
11/18/2024 12:18:46 PM

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:	9/6/2024
Responsible OND Division:	Division of Oncology 3 (DO3)
Application Type and Number:	IND 150904 BLA 761381
Product Name and Strength:	Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) injection 600 mg and 10,000 Units/5 mL (120 mg and 2,000 Units/mL)
Product Type:	Multiple Ingredient Product
Applicant/Sponsor Name:	Bristol Myers Squibb Company (BMS)
FDA Received Date:	October 16, 2023 (IND) February 29, 2024 (BLA)
Nexus NPNS ID #:	2023-212 (IND) 2024-237 (BLA)
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

Reference ID: 5442324

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by BMS for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761381.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On February 29, 2024, BMS submitted a list of 5 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. BMS also provided findings from an external study conducted by (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by BMS:

Table 1. Suffixes submitted by BMS***	
1.	nvhy
2.	(b) (4)
3.	
4.	
5.	

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

[a] Non-proprietary Name Suffix Request BLA 761381. (b) (4) 2024 Feb 29. Available from: ¥¥CDSESUB1¥EVSPROD¥bla761381¥0001¥m1¥us¥ind150904-request-for-nonproprietary.pdf

[b] 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

2.1 nivolumab and hyaluronidase-nvhy

BMS's first proposed suffix, -nvhy, is comprised of 4 distinct letters. We note that the suffix connotes the core name **niv**olumab and **hy**aluronidase. However, DMEPA does not object to suffixes that connote their own core name.

We determined that the proposed suffix -nvhy, 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 September 6, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 3 (DO3) on September 6, 2024.

4 CONCLUSION

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

4.1 Recommendations for Bristol Myers Squibb Company

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

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
09/06/2024 11:42:40 AM

CHI-MING TU
09/06/2024 11:43:36 AM

PROPRIETARY NAME REVIEW

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:	May 8, 2024
Application Type and Number:	BLA 761381
Product Name, Dosage Form, and Strength:	Opdivo Qvantig (nivolumab hyaluronidase-xxxx)[a] injection, 600 mg/10,000 units per 5 mL vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bristol Myers Squibb Co. Bristol Myers
PNR ID #:	2024-1044725652
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, 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 nivolumab hyaluronidase-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

Reference ID: 5378094

1 INTRODUCTION

This review evaluates the proposed proprietary name, Opdivo Qvantig, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the Reference section and Appendix A, respectively. Bristol Myers submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 150904 (see below).

1.1 REGULATORY HISTORY

Bristol Myers previously submitted the proposed proprietary name, (b) (4) ***, under IND 150904 on January 31, 2023. However, on July 12, 2023, we found the name, (b) (4) *** unacceptable because it did not convey that the product was a multi-ingredient formulation. Additionally, the proposed name contained a modifier that was a well-established medical abbreviation and vulnerable to medication errors.[c]

Thus, Bristol Myers submitted the name, Opdivo Qvantig, for review on August 9, 2023 under IND 150904 and we found the name conditionally acceptable on December 18, 2023.[d]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 29, 2024[b], and the prescribing information received on February 29, 2024[e].

Table 1. Relevant Product Information for Opdivo[f] and Opdivo Qvantig

Product Name	**Opdivo (currently marketed)**	**Opdivo Qvantig (proposed)**
Initial Approval Date	12/22/2014	N/A
Application Number	BLA 125554	BLA 761381
Intended Pronunciation	op-DEE-voh	op-DEE-voh cue-VAN-tig.
Nonproprietary name	nivolumab	nivolumab and hyaluronidase

[b] Requested Proprietary Name for nivolumab and hyaluronidase: Opdivo Qvantig. (b) (4) (b) (4); 2023 JULY. Available from: \\CDSESUB1\EVSPROD\bla761381\0001\m1\us\bms986298-req-proprietary-name-rev-opdivoqvantig.pdf

[c] Mahmoud, S. Proprietary Name Review for (b) (4) *** (IND 150904). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 JULY 12. PNR ID No. 2023-1044724964.

[d] Mahmoud, S. Proprietary Name Review for Opdivo Qvantig (IND 150904). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 DEC 18. PNR ID No. 2023-1044725281.

[e] Proposed prescribing information for Opdivo Qvantig. Princeton (NJ): Bristol Myers Squibb Co.; 2024 FEB 29. Available from: \\CDSESUB1\EVSPROD\bla761381\0001\m1\us\initial-bla-nivo-hyal-markup.docx

[f] Opdivo [Prescribing Information]. FDALabel. U.S. Food and Drug Administration. March 2022. [cited 2023 JUN 28]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125554s112lbl.pdf

Indication	Melanoma Non-small cell lung cancer (NSCLC) Malignant pleural mesothelioma Renal cell carcinoma (RCC) Classic Hodgkin Lymphoma (cHL) Squamous Cell Carcinoma of the Head and Neck (SCCHN) Urothelial Carcinoma Colorectal Cancer Hepatocellular Carcinoma (HCC) Esophageal Cancer Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma	For the treatment of melanoma, unresectable or metastatic melanoma, adjuvant melanoma, metastatic non-small cell lung cancer (NSCLC), advanced renal cell carcinoma (RCC), squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma (HCC), gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma.
Route of Administration	Intravenous infusion	Subcutaneous
Dosage Form	Injection	
Strength	40 mg/4 mL (10 mg/mL), 100 mg/10 mL (10 mg/mL), 120 mg/12 mL (10 mg/mL), and 240 mg/24 mL (10 mg/mL)	600 mg nivolumab/10,000 Units hyaluronidase per 5 mL vial
Dose and Frequency	See Opdivo label[g] for currently approved dosing	(b) (4) 600 mg every 2 weeks, or 1,200 mg every 4 weeks (5 mL every 2 weeks, 10 mL every 4 weeks) as single injection in abdomen or thigh. (b) (4) 600 mg every 2 weeks, or 1,200 mg every 4 weeks (5 mL every 2 weeks, 10 mL every 4 weeks) as single injection in abdomen or thigh. (b) (4)

[g] Opdivo [Prescribing Information]. FDALabel. U.S. Food and Drug Administration. March 2022. [cited 2023 JUN

How Supplied	Carton of one single-dose vial	Individual single-dose vial
Storage	Store under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light by storing in the original package until time of use. Do not freeze or shake.	Refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light and freezing.

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Opdivo Qvantig.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Opdivo Qvantig 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 Opdivo Qvantig. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Opdivo Qvantig.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Opdivo Qvantig.

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.[h]

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Bristol Myers did not provide a derivation or intended meaning for the proposed proprietary name, Opdivo Qvantig, in their submission. This proprietary name is comprised of a root name "Opdivo" and modifier "Qvantig" that does not contain any components (i.e. route of administration, dosage form, etc.) that can contribute to medication error. We evaluate the appropriateness of using the same root name for this product and the proposed modifier "Qvantig" in Section 2.2.8 below.

28]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125554s112lbl.pdf

[h] USAN stem search conducted on April 18, 2024.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On March 13, 2024, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Opdivo Qvantig at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Seventy-nine (n=79) practitioners participated in DMEPA's prescription simulation studies for Opdivo Qvantig. Two respondents in the study incorrectly interpreted the product to be 'Opdivo' (1 inpatient, 1 CPOE). The name 'Opdivo' is further analyzed in Section 2.2.8. One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected 'Optivar.' However, the participant entered an incorrect sequence of letters, 'optiv' when searching for the study name. As a result, the CPOE generated picklist did not contain 'Opdivo Qvantig' as a choice. The participant proceeded to incorrectly select 'Optivar' as their response after 32 seconds in order to proceed with the FDA prescription stimulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Despite this, we further evaluated Opdivo Qvantig vs. Optivar and determined that this name pair has sufficient orthographic and phonetic differences. This finding of sufficient differences between the name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[i], which calculates a combined orthographic and phonetic score of 42% indicating low similarity. We further evaluate 'Optivar' in appendix F.

Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[j] identified 11 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated all of the names in our previous proprietary name review. We re-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 name. We note that one of the product characteristics has changed. Prescribing information allows for an additional dosage of 900 mg/15,000 units every 3 weeks for some indications. Taking the additional dosage into account, we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified zero names not previously analyzed.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

[i] POCA search conducted on May 1, 2024 in version 5.7

[j] POCA search conducted on April 18, 2024 in version 5.7.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	0
Low similarity name pair: combined match percentage score ≤54%	1

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 1 names contained in Table 2 determined none of the names will pose a risk for confusion with Opdivo Qvantig as described in Appendices C through H.

2.2.8 SAFETY ANALYSIS OF THE ROOT NAME "OPDIVO" AND THE PROPOSED MODIFIER "QVANTIG"

The proposed proprietary name is comprised of two parts: the root name 'Opdivo' and the modifier 'Qvantig'. The root name, Opdivo, is the proprietary name for a marketed intravenous formulation of nivolumab injection (approved on December 22, 2014 under BLA 125554). Bristol Myers has now developed a co-formulation of nivolumab and hyaluronidase for subcutaneous injection. Bristol Myers proposes the modifier, Qvantig, to evoke the hyaluronidase component of the subcutaneous co-formulation from the currently marketed product, Opdivo, which is administered as an intravenous infusion. We note that Opdivo and Opdivo Qvantig share a therapeutic active ingredient (nivolumab), dosage form, and indication, but differ in strength, dose, route of administration, and how supplied. See Table 1 for a comparison of product characteristics between Opdivo and Opdivo Qvantig.

Given the Applicant's proposal to use 'Opdivo' as the root name with the addition of a modifier, we considered the following: (1) use of the same root name, (2) whether use of modifier is sufficient to adequately distinguish the products, and (3) whether the proposed modifier 'Qvantig' is appropriate.

1. Use of the same root name, Opdivo
Our routine postmarketing surveillance has not identified any signals attributed to name confusion involving Opdivo and both products share a therapeutic active ingredient (nivolumab). Thus, we do not object to the use of the root name, Opdivo, for this product.

2. Whether the use of a modifier is sufficient to distinguish the products
The use of a modifier to differentiate product characteristics between products, such as route of administration, is a common naming practice within a family brand. Modifiers can assist in differentiating products and may help to prevent potential selection errors when used; however, omission and oversight of modifiers is cited in literature as a common cause of

medication errors[k]. Postmarket experience shows that family branding may result in medication errors if the modifier is omitted, and the product characteristics are similar or overlap.

We considered the risk of name confusion between Opdivo and Opdivo Qvantig if the modifier is omitted or overlooked. For example, if the proposed modifier is omitted or overlooked on a prescription or medication order for "Opdivo Qvantig 5 mL subcutaneously every 2 weeks", this may result in 5 mL of the intravenous formulation of Opdivo being dispensed and administered subcutaneously once weekly. This error would result in the patient receiving a wrong dose as 5 mL of the intravenous formulation of Opdivo contains 50 mg of nivolumab instead of the intended 5 mL of the subcutaneous formulation of Opdivo which contains 600 mg of nivolumab.

Further, the addition of hyaluronidase to therapeutic biologic products provides for increased dispersion and absorption, allowing for a larger volume (10 mL) to be injected subcutaneously with limited swelling or pain. Therefore, if 5 mL of the intravenous formulation (without hyaluronidase) is inadvertently administered subcutaneously, nivolumab would be very slowly absorbed, which may potentiate the underdose as the peak concentration would not be achieved, and the patient may experience swelling and pain.

An alternative to using a modifier to distinguish this product from the currently marketed products is to use a different root name. However, marketing the new product under a unique proprietary name also carries a risk of medication errors, such as therapeutic duplication and overdoses.

Although the proposed naming strategy is not devoid of risk because modifiers may be omitted, in this case, we agree that using a modifier may assist in differentiating the current and proposed products. Furthermore, label and labeling mitigations can help minimize the residual risk of product selection or wrong route of administration errors.

3. Whether the use of the modifier "Qvantig" is appropriate.
We considered whether 'Qvantig' itself is a suitable modifier from a safety perspective. The proposed modifier, Qvantig, is a novel modifier, with no known precedent in the United States marketplace. However, it is reasonable to expect that, like any novel modifier, awareness among healthcare practitioners will increase with market uptake of the product. Additionally, we determined that the modifier does not contain any components such as USAN stem, route of administration, or dosage form that is misleading or can contribute to medication error. Thus, it appears to provide adequate differentiation between the currently marketed Opdivo (single ingredient, variable and weight-based dosing, intravenous administration) and the proposed drug product (multiple-ingredient product, fixed dosing of 5 mL or 10 mL, and subcutaneous administration). Thus, we do not object to the modifier 'Qvantig'.

[k] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

In summary, we find the use of the root name, Opdivo, acceptable for the proposed product. Additionally, we find that the addition of the modifier "Qvantig" to the root name Opdivo may assist in differentiating the proposed multi-ingredient, subcutaneously administered product from the currently marketed Opdivo. Therefore, based on the totality of information considered above, we do not object to the proposed name, Opdivo Qvantig, for the proposed product.

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On May 8, 2024, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Opdivo Qvantig, is conditionally acceptable.

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

3.1 COMMENTS TO BRISTOL MYERS SQUIBB CO.

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

If any of the proposed product characteristics as stated in your submission, received on February 29, 2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

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.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs@FDA Glossary of Terms, available at https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[l]

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

[l] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[m]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[m] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary Safety Evaluator assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		

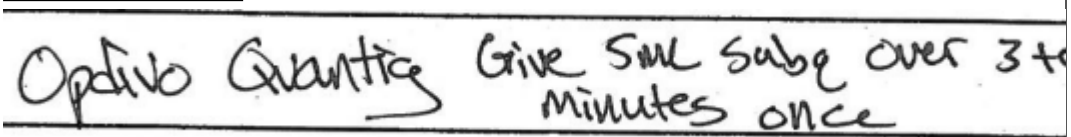
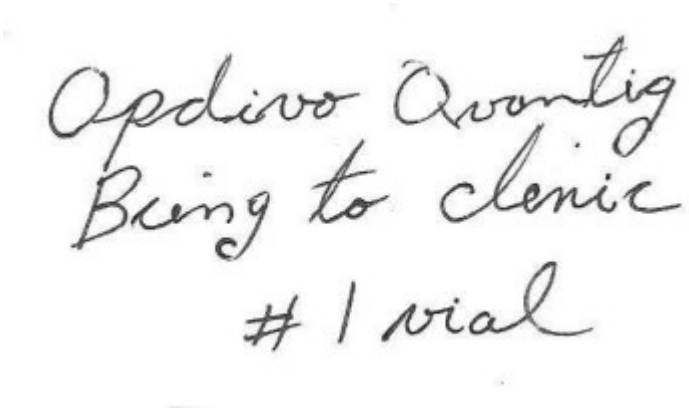
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? • *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤54%).**
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Opdivo Qvantig Study (Conducted on 3/29/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Opdivo Qvantig Bring to clinic #1 vial
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Opdivo Qvantig	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Opdivo Qvantig People Received Study: 166 People Responded: 79					
Total	19	20	18	22	79
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
APDIVO QUANTIG	0	1	0	0	1
APDIVO QVANTIG	0	2	0	0	2
N/A	0	1	0	0	1
OPDIPVO QVANTIC	0	0	1	0	1
OPDIVO	1	0	0	1	2
OPDIVO Q VANTEK	0	0	1	0	1

Reference ID: 5378094

OPDIVO Q VANTIQ	0	0	1	0	1
OPDIVO QUANTIG	9	8	0	0	17
OPDIVO QUANTIQ	1	0	0	0	1
OPDIVO QUVANTIQ	0	0	1	0	1
OPDIVO QUVANTIV	0	0	1	0	1
OPDIVO QVANTIC	0	0	2	0	2
OPDIVO QVANTIG	7	8	0	20	35
OPDIVO QVANTIK	0	0	5	0	5
OPDIVO Q-VANTIK	0	0	1	0	1
OPDIVO QVANTIQ	0	0	5	0	5
OPDIVOQUANTIG	1	0	0	0	1
OPTIVAR	0	0	0	1	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Opdivo Qvantig Pronunciation: op-DEE-voh cue-VAN-tig. Established name: nivolumab hyaluronidase-xxxx Dosage form: injection Strength(s): 600 mg/10,000 units per 5 mL vial Dosage: Nivolumab 600 mg / 10,000 units hyaluronidase subcutaneously every 2 weeks or Nivolumab 1,200 mg / 20,000 units hyaluronidase subcutaneously every 4 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	NA		

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	NA	

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Opdivo Qvantig Pronunciation: op-DEE-voh cue-VAN-tig. Established name: nivolumab hyaluronidase-xxxx Dosage form: injection Strength(s): 600 mg/10,000 units per 5 mL vial Dosage: Nivolumab 600 mg / 10,000 units hyaluronidase subcutaneously every 2 weeks or Nivolumab 1,200 mg / 20,000 units hyaluronidase subcutaneously every 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	NA		

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Optivar	42

APPENDIX G. Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	NA		

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion[n].

No.	Name	POCA Score (%)
1.	NA	

[n] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

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