CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761464Orig1s000

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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Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
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Through:
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Director, Office of Surveillance and Epidemiology
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Subject: Evaluation of the nonproprietary name for BLA 761464

Daiichi Sankyo, Inc. (Daiichi) originally submitted two Biologics License Applications (BLA (b) (4) and BLA 761394) pursuant to Section 351(a) of the Public Health Service Act. BLA (b) (4) for Datroway (datopotamab deruxtecan-xxxx) was submitted on December 20, 2023, to the Division of Oncology 2 (DO2) and BLA 761394 for Datroway (datopotamab deruxtecan-xxxx) was submitted on January 29, 2024, to the Division of Oncology 1 (DO1). DMEPA found the proposed suffix -dlnk acceptable for both BLAs (b) (4) and 761394).[a,b] However, BLA (b) (4) was withdrawn on November 12, 2024. BLA 761394 was approved on January 17, 2025, and the proper name designated in the license is datopotamab deruxtecan-dlnk.[c]

Daiichi Sankyo submitted BLA 761464 pursuant to Section 351(a) of the Public Health Service Act on November 12, 2024, to the Division of Oncology 2 (DO2) and the PDUFA goal date to take action on the application is July 12, 2025 (priority review).

Per Daiichi's Cover Letter, as agreed with the Agency during the Type B Pre-BLA- meeting on November 5, 2024,[d] reference is made to Module 3 Quality, under BLA (b) (4) for all Chemistry, Manufacturing, and Controls (CMC) information. Therefore, the drug substance (DS) and drug product (DP) in the proposed BLA 761464 are the same as the DS and DP in the withdrawn BLA (b) (4) and the approved BLA 761394, and all three BLAs are for the same lyophilized powder formulation in single-dose vials with a single-strength presentations of 100 mg/vial.

The proposed product is a TROP-2-directed antibody and topoisomerase inhibitor conjugate. The proposed BLA 761464 proposes the same formulation, in the same dosage form, strength, 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.[e] Therefore, both the approved 351(a) BLA 761394 and the proposed BLA 761464 are within the scope of this naming guidance.

As such, the proposed nonproprietary name suffix -dlnk was found acceptable for BLA 761394,[f] and the proper name designated in the license is datopotamab deruxtecan-dlnk.[g]

We carefully considered whether the nonproprietary name for the proposed BLA 761464 should include a different distinguishing suffix than that designated for approved BLA 761394 or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating

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[a] (b) (4)
(b) (4)

[b] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761394. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2024 Nov 18. Nexus NPNS ID: 2024-230

[c] Kluetz, P.G. BLA Approval (BLA 761394). Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2025 January 17. Available at: https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af80794944

[d] Aisida B.F. Type B Pre-BLA Meeting Minutes for Datopotamab Deruxtecan IND 136626. Silver Spring (MD): FDA, CDER, OND, DO2 (US); 2024 November 05. Available at: https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af80780939

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

[f] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA 761394. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2024 Nov 18. Nexus NPNS ID: 2024-230

[g] Kluetz, P.G. BLA Approval (BLA 761394). Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2023 December 08. IND 155696. Available at: https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af80794944

the same proper name (i.e., datopotamab deruxtecan-dlnk) for the proposed BLA 761464. Among the factors we have considered are the following:

1. The drug substance (DS) and drug product (DP) in BLA 761464 are the same as the DS and DP in BLA 761394.

2. The formulation, dosage form, strength, dose, and route and frequency of administration are identical for BLA 761394 and BLA 761464. See Appendix A – Product Characteristics Comparison Table for more information.

3. Considering that BLA 761464 share the same DS and DP as BLA 761394, no significant differences in immunogenicity profiles are expected.

4. Under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim.[h] If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original application. Thus, Daiichi submitted separate BLAs. Had one of the BLAs been approved prior to submission of the second indication back in November 2024, the additional indication could be managed under a supplement to the approved BLA, which would not have resulted in a change to the proper name under the approach to nonproprietary naming described in the final guidance.

5. Daiichi is proposing to use the same proprietary name (Datroway) for both of their datopotamab deruxtecan BLAs (BLA 761394 and BLA 761464) and a combined US Prescribing Information (USPI). 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 Datroway acceptable for BLA 761394[i] and BLA 761464.[j]

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 the proposed BLA 761464, datopotamab deruxtecan-xxxx, are the same as the DS and DP in the approved BLA 761394. Also, as noted above, Daiichi is the applicant for BLA 761394 and BLA 761464.

Given the above factors, a different nonproprietary name for BLA 761464 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761464, could create confusion and would not further the goals of the naming convention.

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[h] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

[i] Stewart, J. Proprietary Name Review for Datroway (IND 136626, BLA (b) (4), BLA 761394). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Mar 13. PNR ID No. 2023-1044725525 and 2024-1044725596.

[j] Stewart, J. Proprietary Name Review for Datroway (BLA 761464). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 Feb 05. PNR ID No. 2024-1044726098.

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 761464.[k] 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 Daiichi in an advice letter.

Comments for Daiichi for BLA 761464:

We have determined that datopotamab deruxtecan-dlnk 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.

[k] 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

	(b) (4)		
Proprietary Name		Datroway	Datroway
Application No.		BLA 761394	BLA 761464
Initial Approval/ PDUFA Goal		Approved 1/17/25	PDUFA goal date 7/12/25
Active Ingredient		datopotamab deruxtecan-dlnk	datopotamab deruxtecan-dlnk
Indication		The treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	Proposed: The treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated (EGRFm) non-small cell lung cancer (NSCLC) who have received prior systemic therapies, including an EGFR-directed therapy.
Route of Administration	Intravenous		
Dosage Form	For Injection		
Strength	100 mg		
Dose and Frequency	6 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity		
How Supplied	lyophilized powder in a 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 until time of reconstitution. Do not freeze. Do not shake the reconstituted or diluted solution.		

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
05/27/2025 08:55:29 PM

CHI-MING TU
05/28/2025 06:47:07 AM

GERALD J DALPAN
05/28/2025 07:38:07 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:	February 5, 2025
Application Type and Number:	BLA 761464
Product Name, Dosage Form, and Strength:	Datroway (datopotamab deruxtecan-xxxx)[a] for injection, 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Daiichi-Sankyo, Inc. (Daiichi Sankyo)
PNR ID #:	2024-1044726098
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
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 datopotamab deruxtecan-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Datroway, 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. Daiichi Sankyo submitted an external name study, conducted by (b) (4),[b] for this proposed proprietary name. The submitted external name study was previously reviewed under BLA (b) (4), and BLA 761394 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Daiichi Sankyo previously submitted the proposed proprietary name, Datroway, under BLA (b) (4) on December 20, 2023, and BLA 761394 on January 29, 2024, and we found the name conditionally acceptable on March 13, 2024.[c] Daiichi Sankyo withdrew BLA (b) (4) on November 12, 2024, and BLA 761394 was approved on January 17, 2025.

Thus, Daiichi Sankyo submitted the proposed proprietary name, Datroway, for review on November 12, 2024 under BLA 761464.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission[d] and the prescribing information[e] received on November 12, 2024.

Table 1. Relevant Product Information for Datroway	
Intended pronunciation:	dat roe' way
Nonproprietary name:	datopotamab deruxtecan-xxxx
Indication:	For the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) who have received prior systemic therapies, including an EGFR-directed therapy.
Dosage Form:	for injection
Strength:	100 mg/vial
Route of administration:	Intravenous Infusion

[b] Proprietary Name Safety Summary. (b) (4) 2023 Oct 19. Available from: \\CDSESUB1\EVSPROD\bla761464\0001\m1\us\118-proprietary-names\appendix-2.pdf .

[c] Stewart, J. Proprietary Name Review for Datroway (BLA (b) (4) and BLA 761394). Silver Spring (MD): FDA, CDER, OSE, (US); 2024 Mar 13. PNR ID No. 2023-1044725525 and 2024-1044725.

[d] Request for Proprietary Name Review (BLA 761464 Datroway). Basking Ridge (NJ): Daiichi-Sankyo, Inc.; 2024 Nov 12. Available from: \\CDSESUB1\EVSPROD\bla761464\0001\m1\us\118-proprietary-names\prop-name-request.pdf

[e] Proposed prescribing information for Datroway (BLA 761464). Basking Ridge (NJ): Daiichi-Sankyo, Inc.; 2024 Nov 12. Available from: \\CDSESUB1\EVSPROD\bla761464\0001\m1\us\114-labeling\draft\labeling\us-pi-clean.docx

Table 1. Relevant Product Information for Datroway	
Dose and frequency:	Recommended dose: 6 mg/kg/dose intravenously every 3 weeks Dose modifications for adverse reactions: 1st Dose Reduction: 4 mg/kg/dose 2nd Dose Reduction: 3 mg/kg/dose
How Supplied:	Carton containing one 100 mg single-dose vial
Storage:	Store at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of reconstitution.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Datroway 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 Datroway. The Division of Oncology 2 (DO2) did not comment on the findings of OPDP's assessment for Datroway.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Daiichi Sankyo did not provide a derivation or intended meaning for the proposed proprietary name, Datroway, in their submission. This proprietary name is comprised of a single word that contains the letter string "tr", which is a medical abbreviation for "time-release", which may be used as a modifier to denote that a product is a "time-released formulation". Although we typically discourage the inclusion of medical abbreviations in proprietary names, the location of the "tr" letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the "tr" letter string in this case.

[f] USAN stem search conducted on January 28, 2025.

Beyond the "tr" abbreviation, the proposed name, Datroway, does not contain any other components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 2 (DO2) did not forward any comments or concerns relating to Datroway at the initial phase of the review.

2.2.4 SAFETY ANALYSIS OF THE USE OF THE SAME PROPOSED PROPRIETARY NAME, DATROWAY

The proposed proprietary name, Datroway, is an approved proprietary name currently marketed under Daiichi Sankyo's BLA 761394, which was granted marketing approval on January 17, 2025. As part of the approval process for a separate application, BLA 761464, Daiichi Sankyo submitted the same proprietary name, Datroway, for review.

We note the proposed indication for the pending BLA 761464 is different from the marketed BLA 761394. All other product characteristics remain the same. Table 2 below compares the product characteristics of Datroway under BLA 761394 and BLA 761464.

Table 2. Product Characteristics of Datroway (datopotamab deruxtecan-xxxx)

	Datroway[g]	Datroway (proposed)
Application Number:	BLA 761394 (Approved January 17, 2025)	BLA 761464
Nonproprietary name:	datopotamab deruxtecan-dlnk	datopotamab deruxtecan-xxxx
Indication:	For the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	For the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) who have received prior systemic therapies, including an EGFR-directed therapy. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for

[g] Datroway. DailyMed. National Library of Medicine; January 2025. Available from https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=2950227c-6230-4ca4-a135-46e44d9424a0&type=pdf

		this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.
Dosage Form:	For Injection	
Strength:	100 mg/vial	
Route of Administration:	Intravenous infusion	
Dose and Frequency:	6 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. 1st Dose Reduction: 4 mg/kg/dose 2nd Dose Reduction: 3 mg/kg/dose	
How Supplied:	Carton containing one 100 mg 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 until time of reconstitution. Do not freeze. Do not shake the reconstituted or diluted solution.	

We note that although the indications between the BLAs are different, the different indications will be communicated in the Prescribing Information (PI). Therefore, we do not have safety concerns with the use of Datroway as the proprietary name for both applications.

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

In summary, while we find the proposed naming strategy to use the same proprietary name acceptable from a medication error perspective. Therefore, based on the totality of information considered above, we do not object to the proposed name, Datroway, for the proposed product.

2.2.5 COMMUNICATION OF DMEPA'S DETERMINATION

On February 5, 2025, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

3 CONCLUSION

The proposed proprietary name, Datroway, is conditionally acceptable.

3.1 COMMENTS TO DAIICHI-SANKYO, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 12, 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.[h]

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.

[h] 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 (Tables 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 that 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[i]. 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 are 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 and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

[i] 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

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 as 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>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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 there a different number or</td><td>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 as vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names 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.

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/

JANINE A STEWART
02/05/2025 09:36:23 AM

TINGTING GAO
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