CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

220073Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	April 3, 2025
Application Type and Number:	NDA 220073
Product Name, Dosage Form, and Strength:	Eliquis Sprinkle (apixaban) for oral suspension, 0.15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bristol-Myers Squibb Company (Bristol-Myers Squibb)
PNR ID #:	2025-1044726340
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Eliquis Sprinkle, 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 Squibb submitted an external name study, conducted by (b) (4),[a] for the proposed root proprietary name, Eliquis. The submitted external name study was previously reviewed under IND 066106 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Bristol-Myers Squibb previously submitted the proposed root proprietary name, Eliquis, under IND 066106 and NDA 202155 for apixaban tablets 2.5 mg and 5 mg. We found the name Eliquis acceptable for use on September 9, 2010,[b] December 6, 2011,[c] April 4, 2012,[d] and October 22, 2012.[e] Eliquis 2.5 mg and 5 mg tablets were approved on December 28, 2012 under NDA 202155.

Bristol-Myers Squibb now proposes a 0.15 mg for oral suspension[f] presentation under NDA 220073 for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients (b) (4). The 0.15 mg for oral suspension presentation is packaged in capsules that must be opened and the contents sprinkled into water or infant formula prior to administration.

Bristol-Myers Squibb previously submitted the proposed proprietary name, Eliquis, under NDA 220073 on October 30, 2024 for the 0.15 mg for oral suspension presentation. On January 28, 2025, we found use of the root name, Eliquis, conditionally acceptable for use, however, we identified that the addition of a modifier may help convey the method of preparation and administration of the proposed for oral suspension dosage form and to provide an additional measure of safety to prevent medication errors across the product line.[g]

Thus, Bristol-Myers Squibb withdrew the proposed proprietary name, Eliquis and submitted the proposed proprietary name, Eliquis Sprinkle, for review on March 17, 2025 under NDA 220073.

---

[a] Request for Proprietary Name Review for Eliquis Sprinkle. (b) (4); 2025 MAR 17. Available from: \\CDSESUB1\EVSPROD\nda220073\0026\m1\us\bms562247-req-proprietary-name-rev-eliquis-sprinkle.pdf.

[b] Abdus-Samad, J. Proprietary Name Review for Eliquis (NDA 220073). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2010 SEP 09. PNR ID No. 2010-654.

[c] Walker, M. Proprietary Name Review for Eliquis Sprinkle (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2011 DEC 06. PNR ID No. 2011-3807.

[d] Walker, M. Proprietary Name Review for Eliquis Sprinkle (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2012 APR 04. PNR ID No. 2012-541-1.

[e] Walker, M. Proprietary Name Review for Eliquis Sprinkle (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2012 OCT 22. PNR ID No. 2012-2339.

[f] The Office of Pharmaceutical Quality (OPQ) has determined the dosage form for the proposed 0.15 mg strength that is packaged in capsules is "For oral suspension".

[g] Kundreskas, J. Proprietary Name Review for Eliquis (NDA 220073). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 JAN 28. PNR ID No. 2024-1044726073.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 17, 2025[h] and the prescribing information received on October 17, 2024.[i]

Table 1. Relevant Product Information for Eliquis Sprinkle and Eliquis		
Application Number:	NDA 220073	NDA 202155
Initial Approval Date:	N/A	December 28, 2012
Intended Pronunciation:	ELL-eh-kwiss SPRINK-el	ELL-eh-kwiss
Active Ingredient:	apixaban	
Indication:	• Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation • Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery • Treatment of Deep Vein Thrombosis • Treatment of Pulmonary Embolism • Reduction in the Risk of Recurrence of DVT and PE • Treatment of VTE and Reduction in the Risk of Recurrent VTE in Pediatric Patients **[proposed]**	
Dosage Form:	• for oral suspension	• tablets • *tablets for oral suspension [proposed under supplement]*

Strength:	• 0.15 mg	• tablets: 2.5 mg and 5 mg
		• *tablets for oral suspension [proposed]:* 0.5 mg tablets packaged in sachets as:
		  ○ 0.5 mg
		  ○ 1.5 mg
		  ○ 2 mg

Route of Administration:	oral	

[h] Request for Proprietary Name Review for Eliquis Sprinkle. Princeton (NJ): Bristol-Myers Squibb Company; 2025 MAR 17. Available from: \\CDSESUB1\EVSPROD\nda220073\0026\m1\us\bms562247-req-proprietary-name-rev-eliquis-sprinkle.pdf.

[i] Proposed prescribing information for Eliquis Sprinkle. Princeton (NJ): Bristol-Myers Squibb Company; 2024 OCT 17. Available from: \\CDSESUB1\EVSPROD\nda220073\0001\m1\us\sep2024-pediatric-pas-apixa-markup.pdf.

Table 1. Relevant Product Information for Eliquis Sprinkle and Eliquis	

Dose and Frequency:	• Recommended Dose in Adult Patients
	  ○ Reduction of Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation
	  ▪ 5 mg twice daily
	  ▪ 2.5 mg twice daily for patients with at least two of the following: age greater than or equal to 80 years, body weight less than or equal to 60 kg, serum creatinine greater than or equal to 1.5 mg/dL
	  ○ Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery
	  ▪ 2.5 mg twice daily
	  ○ Treatment of DVT and PE
	  ▪ 10 mg twice daily for 7 days, then 5 mg twice daily
	  ○ Reduction in the Risk of Recurrence of DVT and PE
	  ▪ 2.5 mg twice daily
	• Recommended Dose in Pediatric Patients **[proposed]**
	  ○ Treatment of Venous Thromboembolism (VTE) and Reduction in the Risk of Recurrent VTE in Pediatric Patients
	  ▪ Weight based dosing:
	(b) (4)

Table 1. Relevant Product Information for Eliquis Sprinkle and Eliquis		
How Supplied:	• Bottles of 28	• Tablets ○ 2.5 mg: bottles of 60 and unit dose blister package of 100 ○ 5 mg: bottles of 60, bottles of 74, unit dose blister package of 100 • *Tablets for oral suspension [proposed]* ○ 0.5 mg: carton of 28 sachets: 28 count (1 tablet per sachet), 84 count (3 tablets per sachet), and 112 count (4 tablets per sachet)
Storage:	Store at 20°C to 25°C (68°F-77°F); excursions permitted between 15°C and 30°C (59°F-86°F) [see USP Controlled Room Temperature].	

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Eliquis Sprinkle 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 Eliquis Sprinkle. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Eliquis Sprinkle.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[j] USAN stem search conducted on March 17, 2025.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Bristol-Myers Squibb indicated in their submission that the proposed proprietary name, Eliquis Sprinkle, uses the root name, Eliquis, along with the modifier, Sprinkle, which conveys the instructions for product use (to open the capsules and sprinkle the contents in water or infant formula prior to administering) and is intended to reduce the risk of medication errors that may occur during prescribing between Eliquis and Eliquis Sprinkle.

The root name, Eliquis, contains the letter string "LIQ", which is a medical abbreviation for the dosage form "liquid", and the modifier, Sprinkle, contains the letter string "IN", which is a medical abbreviation for the route of administration "intranasal". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter strings "LIQ" and "IN" are embedded within the infixes of the root and modifier of the proposed proprietary name, respectively, and are unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription and lead to confusion. Thus, in this case we do not object to the inclusion of these letter strings.

Eliquis Sprinkle does not contain any other components (i.e., frequency, etc.) that can contribute to medication errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Eliquis Sprinkle at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-three (83) practitioners participated in DMEPA's prescription simulation studies for Eliquis Sprinkle.

One respondent in the Computerized Prescription Order Entry (CPOE) study omitted the modifier "Sprinkle". We further evaluate the risk of name confusion if the modifier is dropped in Section 2.2.5.

The remaining responses did not overlap with any currently marketed products, nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 SAFETY ANALYSIS OF THE PROPOSED MODIFIER, "SPRINKLE"

The proposed proprietary name, Eliquis Sprinkle, is comprised of the root name, "Eliquis" and the modifier, "Sprinkle". Bristol-Myers Squibb proposes the modifier "Sprinkle" to convey the instructions for product use (to open the capsules and sprinkle the contents on water or infant formula prior to administering) and to reduce the risk of medication errors by differentiating the proposed for oral suspension formulation from the currently marketed tablets and proposed tablets for oral suspension under the root name "Eliquis". As such, we evaluated the following: (1) evaluation of the use of the same root name, (2) use of a modifier to differentiate the product, and (3) evaluation of the proposed modifier, "Sprinkle".

I. Evaluation of the use of the same root name "Eliquis"

Our routine postmarket surveillance has not identified recent name confusion medication errors associated with the root name, "Eliquis". We note that Eliquis and Eliquis Sprinkle share the same active ingredient (apixaban) and the same route of administration (oral), however, the products differ in other characteristics including patient population (pediatric [proposed] and adult vs. pediatric), doses (0.5 mg, 1 mg, 1.5 mg, 2 mg, 3 mg, 4 mg, 6 mg, and 8 mg [proposed], and 2.5 mg, 5 mg, and 10 mg vs. 0.15 mg, 0.3 mg, and 0.6 mg), strength (0.5 mg packaged into 0.5 mg, 1.5 mg, and 2 mg sachets [proposed] and 2.5 mg and 5 mg vs. 0.15 mg), and dosage form (tablet for oral suspension [proposed] and tablet vs. for oral suspension). See Table 1 for a comparison of product characteristics.

II. Evaluation of the use of a modifier to differentiate the product

The use of a modifier to differentiate product characteristics between products, such as a different formulation, is a common naming practice as part of a product line extension. The addition of a modifier to "Eliquis" may help differentiate the proposed for oral suspension formulation from the proposed tablets for oral suspension and currently marketed tablet formulation.

We note that 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 if the modifier is dropped. This was observed in the FDA Prescription Simulation Study, in which one participant in the CPOE study did not record the modifier as part of their response (See Section 2.2.4 above). If this error were to occur the system would require a strength and/or dose. Given there is no overlap in strength between the currently marketed Eliquis product and the proposed product, clarity on the order would need to be obtained. Adult doses of Eliquis are 2.5 mg, 5 mg, and 10 mg and are not directly overlapping, numerically similar, or evenly divisible by 0.15 mg, therefore the risk that adults would be prescribed and dispensed the 0.15 mg for oral suspension presentation is minimized. Additionally, pediatric patients require doses of 0.5 mg to 8 mg and some of these doses are evenly divisible by 0.15 mg. However, the quantity of 0.15 mg capsules needed to obtain these pediatric doses (10, 20, or 40 capsules) would mean that this error is unlikely to reach the patient. Therefore, this type of error may result in a delay of care.

An alternative to using a modifier to distinguish this product from the proposed and 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 and when included it may provide an incremental measure of safety differentiating the products in the product line.

---

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

III. Evaluation of the proposed modifier “Sprinkle”

The Applicant proposes the modifier “Sprinkle” for their product for oral suspension that is packaged in capsules that must be opened and the entire contents sprinkled in water or infant formula prior to administration. We note the modifier “Sprinkle” has been used as a naming convention for other products where the capsules are opened and the contents sprinkled onto food (e.g., Drizalma Sprinkle and Entresto Sprinkle) or must be opened prior to administration (e.g., Alkindi Sprinkle). As the proposed product must be opened and sprinkled into water or infant formula (food) prior to administration, the use of the modifier “Sprinkle” is consistent with its existing meaning and is appropriate for conveying the administration technique of this product formulation. The risks associated with users swallowing the capsule whole will be addressed within the product label and labeling review.

In summary, we find the use of the proposed naming strategy (the use of the same root name, Eliquis, with a distinguishing modifier) acceptable. Additionally, we find the proposed modifier, “Sprinkle”, sufficiently describes the intended preparation and administration of the proposed product and differentiates the proposed product from the proposed and currently marketed Eliquis products. Therefore, based on the totality of information considered above, we do not object to the proposed name, Eliquis Sprinkle, for the proposed product.

2.2.6 COMMUNICATION OF DMEPA’S DETERMINATION

On April 3, 2025, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Eliquis Sprinkle, is conditionally acceptable.

3.1 COMMENTS TO BRISTOL-MYERS SQUIBB COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on March 17, 2025 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.[I]

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.

[I] 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[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 and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[m] 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

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 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?		

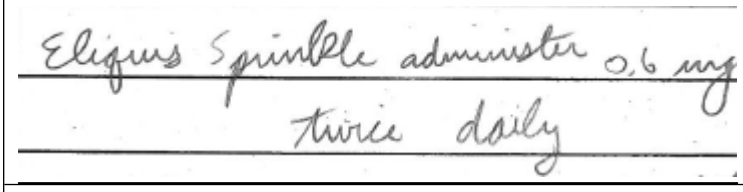
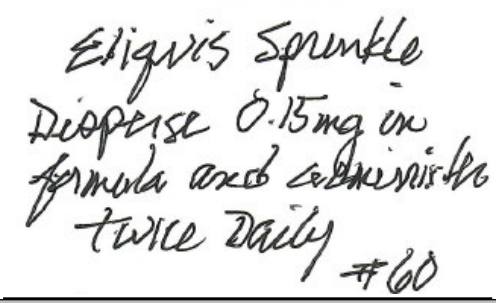
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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 as 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 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.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Eliquis Sprinkle Study (Conducted on 3/24/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Eliquis Sprinkle Disperse 0.15 mg in formula and administer twice daily Dispense 60
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Eliquis Sprinkle	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Eliquis Sprinkle People Received Study: 161 People Responded: 83					
Total	24	22	17	20	83
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ELAQUIST SPRINKLE	0	0	1	0	1
ELIQUIS	0	0	0	1	1
ELIQUIS SPINKLE	0	1	0	0	1
ELIQUIS SPRIKLE	0	1	0	0	1
ELIQUIS SPRINKL	1	0	0	0	1
ELIQUIS SPRINKL3	0	0	1	0	1
ELIQUIS SPRINKLE	22	18	12	19	71
ELIQUIS SPRINKLES	1	1	0	0	2
ELIQUIST SPRINKLE	0	0	1	0	1
ELIQVIS SPRINKLE	0	1	0	0	1
ELLAQUIS SPRINKLE	0	0	1	0	1
ELOQUIS SPRINKLE	0	0	1	0	1

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/

JODY K KUNDRESKAS
04/03/2025 12:41:01 PM

NICOLE F IVERSON
04/03/2025 02:45:02 PM

HINA S MEHTA
04/03/2025 03:44:57 PM

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:	January 28, 2025
Application Type and Number:	NDA 220073
Product Name, Dosage Form, and Strength:	Eliquis (apixaban) capsule, 0.15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bristol-Myers Squibb Company (Bristol-Myers Squibb)
PNR ID #:	2024-1044726073
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Eliquis, 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 Squibb submitted an external name study, conducted by [redacted] (b) (4), [a] for this proposed proprietary name. The submitted external name study was previously reviewed under IND 066106 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Bristol-Myers Squibb previously submitted the proposed proprietary name, Eliquis, under IND 066106 and NDA 202155 for apixaban tablets 2.5 mg and 5 mg. We found the name Eliquis acceptable for use on September 9, 2010,[b] December 6, 2011,[c] April 4, 2012,[d] and October 22, 2012.[e] Eliquis 2.5 mg and 5 mg tablets were approved on December 28, 2012 under NDA 202155.

Bristol-Myers Squibb now proposes a 0.15 mg capsule presentation under NDA 220073 for treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients. Bristol-Myers Squibb has proposed NDA 202155 and NDA 220073 share a Prescribing Information (PI). Additionally, we note the proposed addition of tablets for oral suspension packaged in sachets to NDA 202155/S-040 related to the pediatric indication. See Section 1.2 for additional information.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 30, 2024[f] and the prescribing information received on October 17, 2024.[g]

Table 1. Relevant Product Information for Eliquis NDA 220073 and Eliquis NDA 202155		
Application Number	NDA 220073	NDA 202155
Initial Approval Date	N/A	December 28, 2012

[a] Request for Proprietary Name Review. [redacted] (b) (4); 2024 OCT 30. Available from: \\CDSESUB1\EVSPROD\nda220073\0002\m1\us\nda220073-req-proprietary-name-rev-eliquis.pdf.
[b] Abdus-Samad, J. Proprietary Name Review for Eliquis (IND 066106). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2010 SEP 09. PNR ID No. 2010-654.
[c] Walker, M. Proprietary Name Review for Eliquis (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2011 DEC 06. PNR ID No. 2011-3807.
[d] Walker, M. Proprietary Name Review for Eliquis (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2012 APR 04. PNR ID No. 2012-541-1.
[e] Walker, M. Proprietary Name Review for Eliquis (NDA 202155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2012 OCT 22. PNR ID No. 2012-2339.
[f] Request for Proprietary Name Review for Eliquis (NDA 220073). Princeton (NJ): Bristol-Myers Squibb Company; 2024 OCT 30. Available from: \\CDSESUB1\EVSPROD\nda220073\0002\m1\us\nda220073-req-proprietary-name-rev-eliquis.pdf.
[g] Proposed prescribing information for Eliquis. Princeton (NJ): Bristol-Myers Squibb Company; 2024 OCT 17. Available from: \\CDSESUB1\EVSPROD\nda220073\0001\m1\us\sep2024-pediatric-pas-apixa-markup.pdf.

Table 1. Relevant Product Information for Eliquis NDA 220073 and Eliquis NDA 202155		
Product Name	Eliquis [proposed]	Eliquis
Intended Pronunciation:	ELL-eh-kwiss	
Active Ingredient:	apixaban	
Indication:	• Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation • Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery • Treatment of Deep Vein Thrombosis • Treatment of Pulmonary Embolism • Reduction in the Risk of Recurrence of DVT and PE • Treatment of VTE and Reduction in the Risk of Recurrent VTE in Pediatric Patients **[proposed]**	
Dosage Form:	capsule	• Tablets • Tablets for oral suspension **[proposed]**
Strength:	0.15 mg	• Tablets: 2.5 mg and 5 mg • Tablets for oral suspension **[proposed]**: 0.5 mg tablets packaged in sachets as: ○ 0.5 mg ○ 1.5 mg ○ 2 mg
Route of Administration:	oral	

Table 1. Relevant Product Information for Eliquis NDA 220073 and Eliquis NDA 202155	

Dose and Frequency:	• Recommended Dose in Adult Patients
	  ○ Reduction of Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation
	  ▪ 5 mg twice daily
	  ▪ 2.5 mg twice daily for patients with at least two of the following: age greater than or equal to 80 years, body weight less than or equal to 60 kg, serum creatinine greater than or equal to 1.5 mg/dL
	  ○ Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery
	  ▪ 2.5 mg twice daily
	  ○ Treatment of DVT and PE
	  ▪ 10 mg twice daily for 7 days, then 5 mg twice daily
	  ○ Reduction in the Risk of Recurrence of DVT and PE
	  ▪ 2.5 mg twice daily
	• Recommended Dose in Pediatric Patients **[proposed]**
	  ○ Treatment of Venous Thromboembolism (VTE) and Reduction in the Risk of Recurrent VTE in Pediatric Patients
	  ▪ Weight based dosing:
	(b) (4)

Table 1. Relevant Product Information for Eliquis NDA 220073 and Eliquis NDA 202155		
How Supplied:	Bottles of 28	• Tablets ○ 2.5 mg: bottles of 60 and unit dose blister package of 100 ○ 5 mg: bottles of 60, bottles of 74, unit dose blister package of 100 • Tablets for oral suspension **[proposed]** ○ 0.5 mg: carton of 28 sachets: 28 count (1 tablet per sachet), 84 count (3 tablets per sachet), and 112 count (4 tablets per sachet)
Storage:	Store ELIQUIS at 20°C to 25°C (68°F-77°F); excursions permitted between 15°C and 30°C (59°F-86°F) [see USP Controlled Room Temperature].	

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Eliquis 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 Eliquis. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Eliquis.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[h] USAN stem search conducted on January 7, 2025.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Bristol-Myers Squibb did not provide a derivation or intended meaning for the proposed proprietary name, Eliquis, in their submission. This proprietary name is comprised of a single word that contains the letter string "LIQ", which is a medical abbreviation for the dosage form "liquid". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter string "LIQ" is embedded within the infix of the proposed proprietary name and is unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription and lead to confusion. Thus, in this case we do not object to the inclusion of this letter string.

Eliquis does not contain any other components (i.e., a modifier, route of administration, frequency, etc.) that can contribute to medication errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Eliquis at the initial phase of the review.

2.2.4 EVALUATION OF A SINGLE PROPRIETARY NAME FOR MULTIPLE DOSAGE FORMS

Eliquis is currently marketed as 2.5 mg and 5 mg tablets. Bristol-Myers Squibb is proposing a new formulation, capsule, where the contents of the capsules are sprinkled in water or infant formula and are not to be swallowed whole. We note that the proposed 0.15 mg capsule shares the same active ingredient (apixaban) and route (oral) as the currently approved Eliquis tablets and the proposed tablets for oral suspension under NDA 202155. However, the products differ in some characteristics including patient population (adult vs. pediatric), doses (2.5 mg, 5 mg, or 10 mg vs. 0.15 mg, 0.3 mg, or 0.6 mg), and dosage form (tablet vs. capsule). Table 1 above compares the currently marketed tablet formulation and the proposed capsule formulation.

We note that it is historically accepted practice for some products to have multiple dosage forms share one proprietary name, even when there are other differences in the dosage forms. However, based on our understanding from the Prescribing Information at the time of this review, it is unclear whether the proposed capsule formulation is equivalent on a milligram per milligram basis with the currently approved Eliquis tablets. We find that the adult doses of 2.5 mg, 5 mg, and 10 mg are not directly overlapping, numerically similar, or evenly divisible by 0.15 mg, therefore the risk of adults being prescribed and dispensed the 0.15 mg capsule is minimized. Additionally, we note that the pediatric doses of 1.5 mg, 3 mg, or 6 mg are evenly divisible by 0.15 mg. These doses are indicated for pediatrics 9 kg to less than 12 kg or 18 kg to less than 25 kg which would correspond to a patient 12 years of age or less.[i,j] In general,

[i] 2 to 20 years: Girls Stature-for-age and Weight-for-age percentiles. 2000 MAY. Available from: https://www.cdc.gov/growthcharts/data/set1clinical/cj41c022.pdf
[j] 2 to 20 years: Boys Stature-for-age and Weight-for-age percentiles. 2000 MAY. Available from: https://www.cdc.gov/growthcharts/data/set1clinical/cj41c021.pdf

children age 6 to 11 are capable of safely swallowing a small oral tablet.[k] However, the quantity of 0.15 mg capsules needed to obtain these pediatric doses (10, 20, or 40 capsules) would mean that this error is unlikely to reach the patient. However, this type of error may result in a delay of care.

We note that the proposed 0.15 mg strength does not have product characteristics that are typically described by a modifier (e.g., extended-release formulation or orally disintegrating tablets). However, in some cases modifiers may help provide clues to the correct preparation/administration. The proposed product is packaged in capsules that must be opened and the entire contents sprinkled in water or infant formula and administered via an oral syringe as described in the Instructions for Use (IFU) and should not be swallowed whole. We considered whether the 0.15 mg capsule could be mistaken as a capsule that should be swallowed whole instead of opened. As proposed, the intended patient population for the 0.15 mg capsule are pediatrics between 2.6 and 4.9 kg, which would correspond to a patient age of less than 6 months old.[l,m] This population would not be capable of safely swallowing a capsule whole. However, we are concerned that packaging the product in a dosage form that implies a different method of administration other than the one intended may lead to confusion.[n]

The addition of a modifier to the proprietary name may provide an additional measure to emphasize the nature of preparation/administration of the proposed product and highlight a difference between the proposed capsule and currently marketed tablets.

In conclusion, we agree with the proposal to use the same proprietary root name, Eliquis, for this proposed product. However, when all of the aforementioned concerns are considered in totality, we find that the addition of a modifier to the root name for the 0.15 mg capsule may help distinguish the correct manner of preparation/administration.

2.2.5 COMMUNICATION OF DMEPA'S DETERMINATION

On January 28, 2025, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Eliquis, is acceptable from a safety perspective. However, the proposed proprietary name, Eliquis, does not adequately distinguish the correct manner of preparation/administration for a product that is packaged in a capsule but is not intended to be

---

[k] Meltzer EO, Welch MJ, Ostrom NK. Pill swallowing ability and training in children 6 to 11 years of age. Clin Pediatr (Phila). 2006 Oct;45(8):725-33. doi: 10.1177/0009922806292786. PMID: 16968958.

[l] Birth to 36 months: Girls Length-for-age and Weight-for-age percentiles. 2000 MAY. Available from: https://www.cdc.gov/growthcharts/data/set1clinical/cj41c018.pdf

[m] Birth to 36 months: Boys Length-for-age and Weight-for-age percentiles. 2000 MAY. Available from: https://www.cdc.gov/growthcharts/data/set1clinical/cj41c017.pdf

[n] Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Food and Drug Administration. 2022. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf.

swallowed whole. We provide a recommendation for the Applicant to consider the addition of a modifier to the shared root name, Eliquis, to mitigate these risks.

3.1 COMMENTS TO BRISTOL-MYERS SQUIBB COMPANY

We have completed our review of the proposed proprietary name, Eliquis, and find the use of this root name acceptable.

However, during the course of our review, we identified that the addition of an appropriate modifier with your proposed proprietary name may help to convey the preparation/administration of your proposed capsule dosage form and provide additional measure of safety to prevent medication errors across your product line. To further inform our ongoing review of your application, provide a response by February 05, 2025 stating whether you have considered use of a modifier for this proposed product, and your risk-based justification for use of the root name alone.

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.

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 2. 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.[o]

Table 2. 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)).

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

Table 2. 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	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.
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. 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-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.

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/

JODY K KUNDRESKAS
01/28/2025 11:15:47 AM

NICOLE F IVERSON
01/28/2025 01:47:03 PM

HINA S MEHTA
01/28/2025 02:03:52 PM