CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219531Orig1s000

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:	March 25, 2025
Application Type and Number:	NDA 219531
Product Name, Dosage Form, and Strength:	Sdamlo (amlodipine) powder for oral solution, 2.5 mg, 5 mg, and 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Brillian Pharma Inc. (Brillian Pharma)
PNR ID #:	2025-1044726203
DMEPA 2 Safety Evaluator:	Robbie Kattappuram, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Sdamlo, 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. Brillian Pharma did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Brillian Pharma previously submitted the proposed proprietary name, [(b) (4)]*** under NDA 219531 on October 24, 2024. However, on December 19, 2024, we found the name, [(b) (4)]*** unacceptable due to orthographic similarities and overlapping product characteristics with the proprietary name, [(b) (4)].[a]

Thus, Brillian Pharma submitted the proposed proprietary name, Sdamlo, for review on December 26, 2024 under NDA 219531.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 26, 2024[b].

Table 1. Relevant Product Information for Sdamlo	
Intended pronunciation:	s-DAM-loh
Active ingredient:	amlodipine
Indication:	***Hypertension*** Indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. ***Coronary Artery Disease*** Chronic Stable Angina Vasospastic Angina (Prinzmetal's or Variant Angina) Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%
Dosage Form:	[(b) (4)] for oral solution
Strength:	2.5 mg, 5 mg, and 10 mg
Route of administration:	oral

[a] Topper, C. Proprietary Name Review for [(b) (4)]*** (NDA 219531). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Dec 19. PNR ID No. 2024-1044726026.

[b] Request for Proprietary Name Review Sdamlo (NDA 219531). Edison (NJ): Brillian Pharma Inc.; 2024 Dec 26. Available from: \\CDSESUB1\EVSPROD\nda219531\0005\m1\us\118-proprietary-names\proposed-proprietary-name-amlodipine-0005.pdf .

Table 1. Relevant Product Information for Sdamlo	
Dose and frequency:	**Adults** The usual initial antihypertensive oral dose of Sdamlo is 5 mg once daily, and the maximum dose is 10 mg once daily. Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding Sdamlo to other antihypertensive therapy. Adjust dosage according to blood pressure goals. In general, wait 7 to 14 days between titration steps. Titrate more rapidly, however, if clinically warranted, provided the patient is assessed frequently. Angina: The recommended dose for chronic stable or vasospastic angina is 5–10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. Most patients will require 10 mg for adequate effect. Coronary artery disease: The recommended dose range for patients with coronary artery disease is 5–10 mg once daily. In clinical studies, the majority of patients required 10 mg. (b) (4) The (b) (4) antihypertensive (b) (4) dose in pediatric patients ages 6–17 years is 2.5 mg to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in pediatric patients.

Table 1. Relevant Product Information for Sdamlo	
How Supplied:	**2.5 mg [redacted] for Oral Solution** SDAMLO [redacted] for Oral Solution, 2.5 mg [redacted] is supplied as a power or powder cake packaged in a sealed [redacted], single use high-density polyethylene (HDPE) bottle with a child-resistant cap. NDC 84567-014-51 Supplied in cartons of 10 bottles sealed in an aluminum pouch **5 mg [redacted] for Oral Solution** SDAMLO [redacted] for Oral Solution, 5 mg [redacted] is supplied as a power or powder cake packaged in a sealed [redacted] single use high-density polyethylene (HDPE) bottle with a child-resistant cap. NDC 84567-015-51 Supplied in cartons of 10 bottles sealed in an aluminum pouch **10 mg [redacted] for Oral Solutions** SDAMLO [redacted] for Oral Solution, 10 mg [redacted] is supplied as a power or powder cake packaged in a sealed [redacted], single use high-density polyethylene (HDPE) bottle with a child-resistant cap. NDC 84567-016-51 Supplied in cartons of 10 bottles sealed in an aluminum pouch
Storage:	Store SDAMLO at controlled room temperature, 20° to 25°C (68° to 77°F) excursion permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Store and dispense in original packaging.
Listed Drug:	Norvasc (amlodipine) NDA 019787

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Sdamlo 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 Sdamlo. The Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Sdamlo.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Brillian Pharma indicated in their submission that the proposed proprietary name, Sdamlo, "is derived from "SD" for "Self-Disperse" and "amlo" which is derived from "amlodipine". This proprietary name is comprised of a single word that contains the letter strings "am" and "ml", which are medical abbreviations for "morning or non-drowsy" and "milliliters", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviations "am" and "ml" in the middle of the proposed proprietary name, Sdamlo, makes it unlikely for the "am" and "ml" letter strings 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 "am" and "ml" letter strings in this case.

Beyond these noted abbreviations, we note that Sdamlo does not contain any additional components (i.e., 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 Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Sdamlo at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-four (84) practitioners participated in FDA's prescription simulation studies for Sdamlo. The 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 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[d] identified 32 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

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[c] USAN stem search conducted on February 3, 2025.

[d] POCA search conducted on February 3, 2025 in version 5.9.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	28
Low similarity name pair: combined match percentage score ≤54%	4

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

Our analysis of the 32 names contained in Table 2 determined none of the names will pose a risk for confusion with Sdamlo as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 25, 2025, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Sdamlo, is conditionally acceptable.

3.1 COMMENTS TO BRILLIAN PHARMA INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 26, 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.[e]

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.

[e] 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[f]. 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. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

[f] 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?		

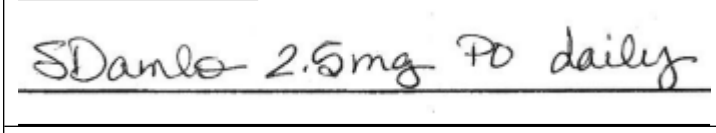
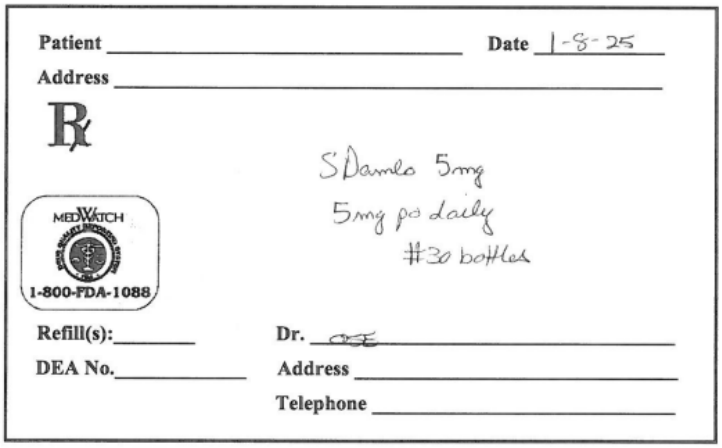
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Sdamlo Study (Conducted on 1/8/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Sdamlo 5 mg Take 5 mg by mouth daily. Dispense # 30 bottles
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Sdamlo	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Sdamlo People Received Study: 167 People Responded: 84					
Total	24	22	17	21	84
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ESDANLO	0	0	2	0	2
ESDEMLO	0	0	1	0	1
ESTAMLO	0	0	9	0	9
ESTANLO	0	0	1	0	1
ESTANLOW	0	0	1	0	1
ESTEMLO	0	0	3	0	3
S DAMLO	0	3	0	0	3
S'DAMLO	0	1	0	0	1

SDAMLO	9	17	0	21	47
SDANLO	14	0	0	0	14
SDARMLO	0	1	0	0	1
SDMALO	1	0	0	0	1

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

No.	Proposed name: Sdamlo Pronunciation: s-DAM-loh Established name: amlodipine Dosage form: powder for oral solution Strength(s): 2.5 mg, 5 mg, and 10 mg Dosage: 2.5 mg to 10 mg by mouth once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Sdamlo	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Tymlos	56
2.	Stalevo	55
3.	Stalevo 100	55
4.	Stalevo 125	55
5.	Stalevo 150	55
6.	Stalevo 200	55
7.	Stalevo 50	55
8.	Stalevo 75	55

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

No.	Proposed name: Sdamlo Pronunciation: s-DAM-loh Established name: amlodipine Dosage form: powder for oral solution Strength(s): 2.5 mg, 5 mg, and 10 mg Dosage: 2.5 mg to 10 mg by mouth once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Stadol	66	This name pair has sufficient orthographic and phonetic differences.
2.	Sildaflo	64	Orthographically, the length of the names differ (6 letters vs. 8 letters) making the name appear dissimilar when scripted. Sdamlo has an upstroke letter 'd' in the second position whereas Sildaflo has a dotted letter 'i' in the same position. Sildaflo contains an upstroke letter 'd' in the fourth position which is absent in the same position of Sdamlo. In addition, Sdamlo contains the rounded letter 'o' in the sixth position while Sildaflo contains an upstroke, crossed letter 'f' in that position. These differences give the names different shapes when scripted. Phonetically, the ending of the first (es vs. sil) and second (dam vs. dah) syllables sound different. The beginning on the third syllable (loh vs. flo) provides additional phonetic differentiation. The name pair differ in dose (2.5 mg to 10 mg vs. apply to thickness of 1/16 of an inch), dosage form (powder for oral solution vs. cream), and route (oral vs. topical). Thus, in this specific case, the risk of name confusion between this name pair is minimized.
3.	Sotalol	58	This name pair has sufficient orthographic and phonetic differences.

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

N/A

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

No.	Name	POCA Score (%)	Failure preventions
1.	Stimlor	67	International product formerly marketed in the United Kingdom.
2.	Tekamlo	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Sudal	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Sudal 12	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Salamol	62	International product marketed in the United Kingdom.
6.	Samson 8	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Sano Log	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Sno Pilo	56	International product formerly marketed in Ireland and the United Kingdom.
9.	Sudal Dm	54	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	Sd Alcohol 40	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	(b) (4) ***	51	Proposed proprietary name for IND 141056 found unacceptable, due to conflict with a marketed product by DMEPA (OSE# 2019-31211118 dated November 14, 2019). Corresponding NDA 214439 was approved on February 24, 2022 under proprietary name Norliqva.
12.	Sandalore	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Duzallo	58
2.	Qdolo	58
3.	Domoso	56
4.	Dopa, Dl	56
5.	Istalol	56
6.	(b) (4) ***	56
7.	Totamol	56
8.	Codimal A	55

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

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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:	December 19, 2024
Application Type and Number:	NDA 219531
Product Name, Dosage Form, and Strength:	(b) (4) (amlodipine) powder for oral solution, 2.5 mg, 5 mg and 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Brillian Pharma Inc. (Brillian)
PNR ID #:	2024-1044726026
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

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