CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219531Orig1s000

OTHER REVIEW(S)

MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	July 22, 2025
Requesting Office or Division:	Division of Cardiology and Nephrology (DCN)
Application Type and Number:	NDA 219531
Product Name, Dosage Form, and Strength:	Sdamlo (amlodipine) powder for oral solution, 2.5 mg/bottle, 5 mg/bottle and 10 mg/bottle
Applicant Name:	Brillian Pharma Inc
FDA Received Date:	July 21, 2025
TTT ID #:	2024-11172-3
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Brillian Pharma Inc submitted revised container labels and carton labeling received on July 21, 2025 for Sdamlo. We reviewed the revised container labels and carton labeling for Sdamlo (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

Brillian Pharma Inc implemented all of our recommendations and we have no additional recommendations at this time.

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[a] Topper, C. Label and Labeling Review for Sdamlo (NDA 219531). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 JUL 18. TTT ID: 2024-11172-2.

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CHRISTINA A TOPPER
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MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	July 18, 2025
Requesting Office or Division:	Division of Cardiology and Nephrology (DCN)
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
Applicant Name:	Brillian Pharma Inc
FDA Received Date:	July 17, 2025
TTT ID #:	2024-11172-2
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Brillian Pharma Inc submitted revised container labels and carton labeling received on July 17, 2025 for Sdamlo. We reviewed the revised container labels and carton labeling for Sdamlo (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The container labels and carton labeling are unacceptable from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error for Brillian Pharma Inc in Section 3.

3 RECOMMENDATIONS FOR BRILLIAN PHARMA INC

A. General Comments (Container Labels and Carton Labeling)

1. We recommend revising the strength statements [e.g. “2.5 mg” to state “2.5 mg per bottle”] to make it clear that the designated strength is per unit so there is no confusion as to how much product is contained in a single unit.
2. The 2.5 mg strength is not clearly differentiated due to the similarity in the (b) (4) color which also overlaps with the font color used for the proprietary name. Lack of adequate differentiation may contribute to wrong strength errors. Color differentiation is most effective when the color used has no association with a particular feature and there is no pattern in the application of the color scheme. We recommend revising the color scheme of the 2.5 mg strength such that the strength and the proprietary name appear in their own unique colors that do not overlap.

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[a] Topper, C. Label and Labeling Review for Sdamlo (NDA 219531). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 JUL 14. TTT ID: 2024-11172-1.

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CHRISTINA A TOPPER
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MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	July 14, 2025
Requesting Office or Division:	Division of Cardiology and Nephrology (DCN)
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
Applicant Name:	Brillian Pharma Inc
FDA Received Date:	July 1, 2025
TTT ID #:	2024-11172-1
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS

1 PURPOSE OF MEMORANDUM

Brillian Pharma Inc submitted revised container labels and carton labeling received on July 1, 2025 for Sdamlo. We reviewed the revised container labels and carton labeling for Sdamlo (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The container labels and carton labeling are unacceptable from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error for Brillian Pharma Inc in Section 3.

3 RECOMMENDATIONS FOR BRILLIAN PHARMA INC

A. Container Labels

1. As currently presented, the package type term "Single-dose" is inconsistent with the package type term on the carton labeling (i.e. Single-Dose Bottles). We recommend revising the package type term on the container labels to "Single-Dose Bottle" for clarity and consistency with the carton labeling.

B. Carton Labeling

1. As currently presented, there is a spelling error (i.e. sigle-dose) under the "Important information:". To correct the spelling error, we recommend revising "sigle-dose" to "single-dose" on the carton labeling.
2. As currently presented, there is inconsistent terminology used to describe the [(b) (4)] bottle which may cause confusion. Under "Important information:", we recommend revising the third and fourth bullets by replacing the word [(b) (4)]" with the word "bottle" for consistency with the rest of the labeling.
3. As currently presented, the bullets under "Important Information:" lack clarity. We recommend revising the bullets as follows:
    a. Revise the first bullet to read "Open the carton and remove the pouch when you plan to start taking the medication. Each pouch contains 10 single-dose bottles on a tray. Remove the dose using one bottle from the tray and store the remaining bottles in the original packaging."
    b. Revise the second bullet to read "Remove the cap from the bottle and peel off the seal when you are ready to mix and take the medication."

[a] Topper, C. Label and Labeling Review for Sdamlo (NDA 219531). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 JUN 02. TTT ID: 2024-11172.

c. Revise the third bullet to read "After the seal is peeled off, reconstitute the content of the bottle with water as soon as possible. Refer to the IFU for preparation and administration instructions."

4. As currently presented, the statement, "Reconstitute with Water Prior to Use" appears less prominent and may be overlooked. We recommend increasing the prominence of this statement by relocating it to the PDP underneath the net quantity statement. If space is a concern, we suggest relocating the statement "KEEP OUT OF REACH OF CHILDREN" to the side panel.

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CHRISTINA A TOPPER
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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	June 25, 2025
To:	Sabry Soukehal, RAC, DCPM Senior Regulatory Health Project Manager **Division of Cardiology and Nephrology (DCN)**
Through:	Barbara Fuller, MSN, BSN, RN Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Laurie Buonaccorsi, PharmD Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Meena Savani, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Instructions for Use (IFU)
Drug Name (established name):	SDAMLO (amlodipine besylate)
Dosage Form and Route:	for oral solution
Application Type/Number:	NDA 219531
Applicant:	Brillian Pharma Inc.

1 INTRODUCTION

On July 19, 2024, Brillian Pharma Inc. submitted for the Agency's review an original New Drug Application (NDA) 219531 for SDAMLO (amlodipine besylate) for oral solution, which was received by the Agency on September 24, 2024. This 505(b)(2) application references NORVASC (amlodipine besylate) tablets (NDA 019787). With this submission, the Applicant proposes indications for the treatment of hypertension and coronary artery disease (chronic stable angina, vasospastic angina, and angiographically documented coronary artery disease without heart failure or an ejection fraction <40%).

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a requests by the Division of Cardiology and Nephrology (DCN) on June 20, 2025, and June 12, 2025, for DMPP and OPDP, respectively, to review the Applicant's proposed Instructions for Use (IFU) for SDAMLO (amlodipine besylate).

DMPP conferred with the Division of Medication Error, Prevention, and Analysis (DMEPA) and a separate DMEPA review of the IFU was completed on June 3, 2025.

2 MATERIAL REVIEWED

- Draft SDAMLO (amlodipine besylate) IFU submitted on July 19, 2024 and received by the Agency on September 24, 2024, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on June 20, 2025.
- Draft SDAMLO (amlodipine besylate) Prescribing Information (PI) submitted on July 19, 2024 and received by the Agency on September 24, 2024, revised by the Review Division throughout the review cycle, and received by DMPP on June 20, 2025 and OPDP on June 2, 2025.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the IFU, the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the IFU using Arial font.

In our collaborative review of the IFU we:

- simplified wording and clarified concepts where possible

- ensured that the IFU is consistent with the PI
- removed unnecessary or redundant information
- ensured that the IFU is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the IFU meets the criteria as specified in both the FDA Guidance for Useful Written Consumer Medication Information (published July 2006) and Instructions for Use-Patient Labeling for Human Prescription Drug and Biological Products (published July 2022)

4 CONCLUSIONS

The IFU is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the IFU is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the IFU.

Please let us know if you have any questions.

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BARBARA A FULLER
06/25/2025 02:30:57 PM

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: June 12, 2025

To: Sabry Soukehal, Senior Regulatory Project Manager
The Division of Cardiology and Nephrology (DCN)

Michael Monteleone, MS, RAC
Associate Director for Labeling, DCN

From: Meena Savani, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sapna Shah, Team Leader, OPDP

Subject: OPDP Labeling Comments for SDAMLO (amlodipine besylate) for oral solution.

NDA: 219531

Background:
In response to the consult request dated March 13, 2025, OPDP has reviewed the proposed Prescribing Information (PI) and carton and container labeling for the original NDA submission for SDAMLO (amlodipine besylate) for oral solution.

PI
OPDP's review of the proposed PI is based on the draft labeling e-mail to OPDP on June 2, 2025, and our comments are provided below.

Carton and Container Labeling:
OPDP's review of the proposed carton and container labeling is based on the draft labeling submitted by the sponsor to the electronic document room on March 7, 2025, and our comments are provided below.

Thank you for your consult. If you have any questions, please contact Meena Savani at 240-402-1348 or Meena.Savani@fda.hhs.gov.

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MEENA R SAVANI
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LABEL AND LABELING 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)

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Date of This Review:	June 2, 2025
Requesting Office or Division:	Division of Cardiology and Nephrology (DCN)
Application Type and Number:	NDA 219531
Product Name, Dosage Form, and Strength:	Sdamlo[a] (amlodipine) for oral solution, 2.5 mg, 5 mg and 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant Name:	Brillian Pharma Inc
FDA Received Date:	March 7, 2025
TTT ID #:	2024-11172
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS

[a] The Proprietary Name, Sdamlo has not yet been approved for this product and is currently under review at the time of this Label and Labeling Review.

1 INTRODUCTION

As part of the approval process for Sdamlo (amlodipine) for oral solution, we reviewed the proposed Sdamlo Prescribing Information (PI), Patient Package Insert (PPI), Instructions for Use (IFU), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

Sdamlo (amlodipine) is a proposed 505(b)(2) drug product and the Listed Drug (LD) is Norvasc (amlodipine), NDA 019787.

2 MATERIALS REVIEWED

This section lists the materials considered for our review of NDA 219531.

Table 1. Materials Considered for this Label and Labeling Review	
Material(s) Reviewed	Appendix Section
Relevant Product Information	A
Labels and Labeling	B
Previous DMEPA Reviews	C
Information request (IR)	D

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed Prescribing Information (PI), Patient Package Insert (PPI), Instructions for Use (IFU), container labels, and carton labeling for Sdamlo to identify deficiencies that may lead to medication errors and other areas of improvement.

We note that during the review cycle, the Office Pharmaceutical Quality (OPQ) revised the dosage form from "(b) (4)" to "for Oral Solution". As such, we recommend that the dosage form is revised on the proposed labels and labeling.

4 CONCLUSION

The proposed Sdamlo Prescribing Information (PI), Patient Package Insert (PPI), Instructions for Use (IFU), container labels, and carton labeling may be improved to promote safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed recommendations to minimize the risk for medication error for the Division of Cardiology and Nephrology (DCN) in Section 5 and for Brillian Pharma Inc in Section 6.

5 RECOMMENDATIONS FOR THE DIVISION OF CARDIOLOGY AND NEPHROLOGY (DCN)

A. Highlights of Prescribing Information (HPI) and Full Prescribing Information

1. Throughout the PI, there are several instances where the dosage form, "powder" is misspelled as "power". We recommend revising "power" to read "powder" throughout the PI.
2. The dosage form is listed as [redacted] in the title, which is inconsistent with the presentation of the dosage form throughout the rest of the PI and on the container labels and carton labeling. OPQ has confirmed that the dosage form is "for Oral Solution". For consistency throughout the labeling, we recommend revising the dosage form to read "for Oral Solution".

B. Highlights of Prescribing Information

1. Dosage and Administration
   a. As currently presented, the route of administration is missing. We recommend revising the dosage statement to include the route of administration, "orally" as noted in track changes below:

[redacted]

C. Full Prescribing Information

1. Section 2 Dosage and Administration
   a. For consistency with the HPI and improved readability, we recommend revising the subheadings in Section 2.1 as noted in Figure 1.
   b. For consistency with the terminology in the text (i.e. "[redacted]"), we recommend revising the subheading in Section 2.2 to "Recommended Dosage in [redacted]" (see Figure 1).
   c. As currently presented, the route of administration is missing from the dosing information, which may lead to confusion and wrong administration errors. For clarity, we recommend adding the route of administration to the dosing information (see Figure 1).
   d. As currently presented, the dosage range contains a dash symbol (i.e. "5-10 mg") as well as the age range in Section 2.2 (i.e., "6-17 years"). The use of symbols instead of the intended meaning may lead to

misinterpretation and medication error. To increase clarity and improve readability, we recommend revising Section 2 as noted in Figure 1.

Figure 1

e. As currently presented, Section 2.3 (b) (4) lacks clarity, which may lead to wrong preparation medication errors or degraded drug product errors. We recommend the following revisions:
    i. Section 2.3 (b) (4) contains instructions for administration, thus we recommend revising the section title to, "Section 2.3 Preparation and Administration of Sdamlo for Oral Solution".
    ii. Remove the (b) (4) bullet that references (b) (4)
    iii. Revise the (b) (4) bullet to include a specific amount and temperature of water in mL to measure and add to the container. For example, "Use one tablespoon to measure 15 mL of room temperature water. Add the 15 mL of water to the container."
    iv. Add an additional bullet to include instructions on consuming the contents of the container immediately or within 60 minutes for consistency with the IFU.

v. Add an additional bullet to include instructions on rinsing for consistency with the IFU.

2. Section 16 How Supplied/Storage and Handling

   a. As currently presented, the first temperature numerical is missing the degree symbol. For clarity, we recommend revising the storage statement to read “Store at 20°C to 25°C (68°F to 77°F) excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].”.

   b. As currently presented, the (b) (4) is listed in the how supplied description, which may be misinterpreted (b) (4). We recommend removing the (b) (4) from the description.

D. (b) (4)

E. Instructions for Use (IFU)

1. As currently presented, the dosage form is presented in parenthesis next to the proprietary name, which is inconsistent with the rest of the labels and labeling. We recommend removing the parenthesis surrounding the dosage form.

2. This product is intended to be reconstituted by the patient or caregiver prior to administration; however, this information is missing from the Instructions for

Use. Not including this statement may result in the product being prepared without reconstitution. We recommend adding the following statement to ensure that patients prepare and administer the product as instructed: "(b) (4)."

3. As currently presented, the IFU does not provide clear instructions on the amount of water needed to be added to the bottle to dissolve the powder. Failure to include clear instructions may lead to wrong dose or preparation errors. Additionally, (b) (4). We recommend (b) (4) include the specific volume and temperature of water needed in tablespoonfuls and milliliters to add to the container. For example, "Use one tablespoon to measure 15 mL of room temperature water. Add the 15 mL of water (b) (4)."

6 RECOMMENDATIONS FOR BRILLIAN PHARMA INC

A. General Comments (Container Labels and Carton Labeling)

1. The proprietary name is presented in all capital letters. We recommend revising the presentation of the proprietary name from all capitals (e.g., SDAMLO) to title case (e.g., Sdamlo) for readability.
2. The first letters of the established name, Amlodipine (b) (4) is capitalized and is inconsistent with the prescribing information (PI). Inconsistencies in established name between the label and labeling and the PI may lead to confusion. We recommend revising the established name to "amlodipine (b) (4) for consistency with the PI.
3. As currently presented, the dosage form is (b) (4). This is inconsistent with the PI. For consistency with the PI, we recommend relocating the dosage form (b) (4), either on the same line or directly below the established name.
4. As currently presented, the format for the expiration date is not defined. We are unable to assess the proposed expiration date format from a medication safety perspective. To minimize confusion and reduce the risk for deteriorated drug medication errors, we recommend identifying the expiration date format you intend to use. FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format if only numerical characters are used or in YYYY-MMM-DD if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, to be expressed as: YYYY-MM if only numerical characters are used or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or forward slash to separate the portions of the expiration date. See *Guidance for*

Industry: Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers (June 2021).

5. As currently presented, the Rx only statement appears prominent, which may compete with other important information on the label. We recommend decreasing the prominence by reducing the font size for the Rx only statement.
6. As currently presented, there is inadequate differentiation between the proposed amlodipine strengths (2.5 mg, 5 mg and 10 mg) (b) (4) . Lack of adequate differentiation may lead to wrong strength errors. Color differentiation is most effective when the color used has no association with a particular feature and there is no pattern in the application of the color scheme. We recommend using different colors to ensure adequate differentiation between the strengths for the container labels and carton labeling. *See Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (May 2022).*
7. This product is intended to be reconstituted by the patient or caregiver prior to administration; however, this information is missing from the container labels and carton labeling. Not including this statement may result in the product being dispensed without reconstitution. We recommend adding the following statement to ensure that patients prepare and administer the product as instructed: "Reconstitute with water prior to use."

B. Container Labels

1. As currently presented, the first temperature numerical is missing the unit of measurement, which may lead to confusion and possible storage errors. For clarity, we recommend revising the storage statement to read "Store at 20°C to 25°C (68°F to 77°F)".
2. The statement of dosage is missing from the container labels. Requirement per 21 CFR 201.55 that labels for prescription drugs bear a statement of the recommended dosage. We recommend adding the statement "Dosage: see Prescribing Information."
3. On the principal display panel, we recommend removing the (b) (4) (b) (4)" from the dosage form as this is inconsistent with the carton labeling.
4. The container label includes the statement (b) (4)" which suggests that (b) (4). This may lead to confusion and wrong dose errors. We recommend removing the statement, " (b) (4)".
5. The container label states (b) (4) ." which conflicts with the IFU statement " (b) (4)

[redacted]." We recommend revising this statement to be consistent with the PI and carton labeling.

C. Carton Labeling

1. As currently presented, the strength statement is listed [redacted] which is inconsistent with the container labels and may lead to confusion. To ensure consistency with the container labels, we recommend removing the [redacted] from the strength statement.
2. As currently presented, the first temperature numerical is missing the degree symbol, which may lead to confusion. For clarity, we recommend revising the storage statement to read "Store at 20°C to 25°C (68°F to 77°F) excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].".
3. As currently presented, the terminology within the statement of dosage statement (i.e., "[redacted]") is inconsistent with the terminology in the Prescribing Information. To ensure consistency with the terminology in the Prescribing Information, we recommend revising the statement of dosage statement to read, "Dosage: see Prescribing Information."
4. On the principal display panel, we recommend revising the package type term "[redacted]" to read "10 single-dose bottles" for consistency with the container labels.

APPENDICES: METHODS AND RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. RELEVANT PRODUCT INFORMATION

Table 2 presents relevant product information for Sdamlo received on March 7, 2025 from Brillian Pharma Inc, and the Listed Drug (LD).

Table 2. Relevant Product Information for Sdamlo and the Listed Drug (LD).		
Product Name	Sdamlo	Norvasc[b] (NDA 019787)
Initial Approval Date	N/A	July 31, 1992
Active Ingredient	amlodipine	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	for oral solution	tablets
Strength	2.5 mg, 5 mg and 10 mg	2.5 mg, 5 mg, 10 mg
Route of Administration	Oral	Oral

[b] Norvasc [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. October 2017. [cited 2025 MAR 06]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019787s062lbl.pdfm.

Table 2. Relevant Product Information for Sdamlo and the Listed Drug (LD).		
Product Name	Sdamlo	Norvasc[b] (NDA 019787)
Dose and Frequency	<u>Adults</u> • The usual initial antihypertensive oral dose 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 amlodipine 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 2. Relevant Product Information for Sdamlo and the Listed Drug (LD).		
Product Name	Sdamlo	Norvasc[b] (NDA 019787)
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	2.5 mg Tablets NORVASC – 2.5 mg Tablets (amlodipine besylate equivalent to 2.5 mg of amlodipine per tablet) are supplied as white, diamond, flat-faced, beveled edged engraved with “NORVASC” on one side and “2.5” on the other side and supplied as follows: • NDC 0069-1520-68 Bottle of 90 5 mg Tablets NORVASC – 5 mg Tablets (amlodipine besylate equivalent to 5 mg of amlodipine per tablet) are white, elongated octagon, flat-faced, beveled edged engraved with both “NORVASC” and “5” on one side and plain on the other side and supplied as follows: • NDC 0069-1530-68 Bottle of 90 • NDC 0069-1530-41 Unit Dose package of 100 • NDC 0069-1530-72 Bottle of 300 10 mg Tablets NORVASC – 10 mg Tablets (amlodipine besylate equivalent to 10 mg of amlodipine per tablet) are white, round, flat-faced,

Table 2. Relevant Product Information for Sdamlo and the Listed Drug (LD).		
Product Name	Sdamlo	Norvasc[b] (NDA 019787)
	packaged in a sealed (b) (4) 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	beveled edged engraved with both “NORVASC” and “10” on one side and plain on the other side and supplied as follows: • NDC 0069-1540-68 Bottle of 90 • NDC 0069-1540-41 Unit Dose package of 100
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.	Store bottles at controlled room temperature, 59° to 86°F (15° to 30°C) and dispense in tight, light-resistant containers (USP).

APPENDIX B. LABELS AND LABELING

B.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[c] along with postmarket medication error data, we reviewed the following Sdamlo labels and labeling submitted by Brillian Pharma Inc.

- Prescribing Information received on March 7, 2025, available from \\CDSESUB1\EVSPROD\nda219531\0007\m1\us\114-labeling\draft\labeling\seldisam-insert_draft-word.docx
- Instruction for Use received on March 7, 2025, available from \\CDSESUB1\EVSPROD\nda219531\0007\m1\us\114-labeling\draft\labeling\instructions_for_use_draft-word.docx
- Patient Prescribing Information received on March 7, 2025, available from \\CDSESUB1\EVSPROD\nda219531\0007\m1\us\114-labeling\draft\labeling\medication_guide_draft-word.docx
- Container labels received on March 7, 2025
- Carton labeling received on March 7, 2025

4 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[c] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

APPENDIX C. PREVIOUS DMEPA REVIEWS

On March 10, 2025, we searched for previous DMEPA reviews relevant to this current review using the terms, “amlodipine”. Our search identified five previous reviews, and we considered our previous recommendations to see if they are applicable for this current review.

Table 3. List of Previous DMEPA Reviews for amlodipine

Application #	Product name	Applicant	Strength	Status	Previous DMEPA Reviews
NDA 214439	Norliqva (amlodipine) Oral solution	CMP Development, LLC	1 mg/mL	02/24/2022	2024-10218 2024-10218-1 2020-1308 2020-1308-1
NDA 211340	Amlodipine Oral suspension	Silvergate Pharmaceuticals, Inc.	1 mg/mL	07/08/2019	2018-2140
NDA 219531	Sdamlo (amlodipine) for oral solution	Brillian Pharma Inc	2.5 mg, 5 mg and 10 mg	Subject of this review	2024-11172

APPENDIX D. INFORMATION REQUEST (IR)

As requested from the Applicant, in an Information Request received on January 26, 2025 (available from https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af80796ad0), Brillian provided two (2) empty samples of the proposed 2.5 mg, 5 mg, and 10 mg products, each including an aluminum pouch containing a white plastic tray with ten labeled bottles and carton labeling.

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/

CHRISTINA A TOPPER
06/02/2025 10:20:08 AM

NICOLE F IVERSON
06/03/2025 07:27:53 AM

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 5/5/2025

TO: Division of Cardiology and Nephrology (DCN)
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 219531

The Office of Study Integrity and Surveillance (OSIS) determined that an inspection is not needed for the site listed below. The rationale for this decision is noted below.

Rationale

The Office of Inspections and Investigations (OII) conducted an inspection of the site in March 2025. The inspection was conducted under the following submission: ANDA non-responsive.

The following items were discussed with the site:

- Failure to maintain documentation specifically noting that a subject was queried for adverse events.
- Failure to document the occurrence of an adverse event in the CRFs at the timepoint where it occurred.

After review of the discussion items, OSIS concluded that the findings did not impact data integrity or subject safety and that the data were reliable.

Site

Facility Type	Facility Name	Facility Address
Clinical	Accutest Research Laboratories Pvt., Ltd.	1st and 2nd Floor, Synergy Square Complex, Krishna Industrial Estate, BIDC Gorwa, Vadodara, Gujarat, India

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/s/

JAMES J LUMALCURI
05/05/2025 09:31:27 AM

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1/24/2025

TO: Division of Cardiology and Nephrology (DCN)
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 219531

The Office of Study Integrity and Surveillance (OSIS) determined that an inspection is not needed for the site listed below. The rationale for this decision is noted below.

Rationale

OSIS conducted a Remote Regulatory Assessment (RRA) for the site in (b) (4). The RRA was conducted under the following submissions: ANDAs non-responsive

OSIS concluded that data from the reviewed studies were reliable.

Site

Facility Type	Facility Name	Facility Address
Analytical	(b) (4)	

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/

WENDY NG
01/24/2025 05:11:00 PM