CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214439Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	September 28, 2021
Application Type and Number:	NDA 214439
Product Name and Strength:	Norliqva (amlodipine) oral solution, 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development, LLC (CMP)
PNR ID #:	2021-1044724149
DMEPA 2 Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Norliqva. CMP previously submitted the proposed proprietary name, Norliqva, under NDA 214439 on November 12, 2020 and it was found conditionally acceptable on January 6, 2021.[a] However, NDA 214439 received a Complete Response Letter on April 22, 2021. Thus, CMP resubmitted the name, Norliqva, under NDA 214439 for review on August 25, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Norliqva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Norliqva.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 16, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Norliqva.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Cardiology and Nephrology (DCN). At that time we also requested additional information or concerns that could inform our review. On September 27, 2021, the Division of Cardiology and Nephrology (DCN) stated no additional concerns with the proposed proprietary name, Norliqva.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Norliqva, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

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[a] Aidoo, M. Proprietary Name Review for Norliqva (NDA 214439). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JAN 6. PNR ID No. 2020-43888044.

3.1 COMMENTS TO CMP DEVELOPMENT, LLC

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

If any of the proposed product characteristics as stated in your submission, received on August 25, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

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/

MARIETTE A AIDOO
09/28/2021 07:31:10 AM

HINA S MEHTA
09/29/2021 01:44:40 PM

CHI-MING TU
10/01/2021 10:26:02 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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 6, 2021
Application Type and Number:	NDA 214439
Product Name and Strength:	Norliqva (amlodipine) oral solution, 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP DEVELOPMENT LLC (CMP)
Panorama #:	2020-43888044
DMEPA Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Norliqva, 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. CMP submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

CMP previously submitted the proposed proprietary name, (b) (4)*** on July 17, 2020. However, DMEPA found the name, (b) (4)*** unacceptable due to orthographic and phonetic similarities and shared product characteristics with the proprietary name, (b) (4)*** (b) (4) (NDA (b) (4)) under OSE # (b) (4) on October 13, 2020.[a]

Thus, CMP submitted the name, Norliqva, for review on November 12, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 12, 2020.

- Intended Pronunciation: nor lik' vah
- Active Ingredient: amlodipine
- Indication of Use:
    - 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%
- Route of Administration: Oral
- Dosage Form: oral solution
- Strength: 1 mg/mL
- Dose and Frequency:
    - Adult recommended starting dose: 5 mg once daily with maximum dose 10 mg once daily.

[a] Mena-Grillasca, C. Proprietary Name Review for (b) (4) (NDA 214439). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 OCT 13. Panorama No. 2020-41453552.

        - Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5 mg once daily.
    - Pediatric starting dose: 2.5 mg to 5 mg once daily.
- How Supplied: 150 mL amber glass bottles with a child-resistant closure
- Storage: Store at 20°C -25°C (68-77°F); excursion permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- Reference Listed Drug/Reference Product: Norvasc NDA 019787

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Norliqva would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Norliqva.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

CMP did not provide a derivation or intended meaning for the proposed proprietary name, Norliqva, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 1, 2020 e-mail, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Norliqva at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-nine practitioners participated in DMEPA's prescription studies for Norliqva. The responses did not overlap with any currently marketed products nor did the responses sound or

[b] USAN stem search conducted on December 8, 2020.

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[c] identified 67 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	60
Low similarity name pair: combined match percentage score ≤54%	10

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 73 names contained in Table 1 determined none of the names will pose a risk for confusion with Norliqva as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiology and Nephrology (DCN) via e-mail on December 29, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiology and Nephrology (DCN) on January 6, 2021, they stated no additional concerns with the proposed proprietary name, Norliqva.

3 CONCLUSION

The proposed proprietary name, Norliqva, is acceptable.

[c] POCA search conducted on December 8, 2020 in version 4.4.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at (240) 402-4156.

3.1 COMMENTS TO CMP DEVELOPMENT LLC

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

A request for proprietary name review for Norliqva should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on November 12, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN 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 http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

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).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP 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 DNDP 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. [d]

[d] 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	**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.
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, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

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

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- 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[e]. 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 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) 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

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

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 staff also conducts a 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) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP 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 reviewer 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 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: 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.

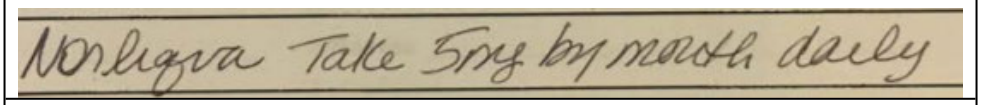
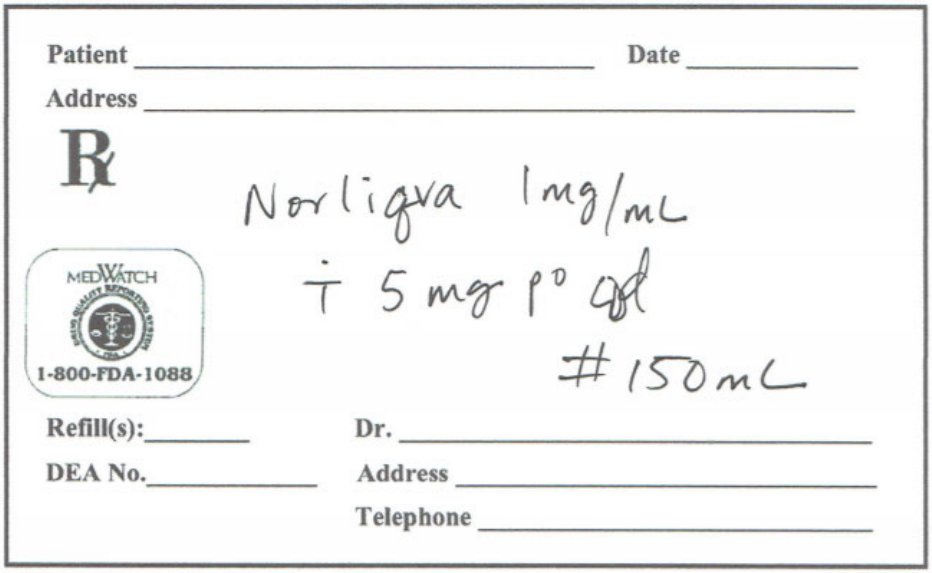
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: 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. Norliqva Study (Conducted on November 27, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Norliqva 1mg/mL Take 5 mg po once daily. Dispense: 150 mL
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
NORLIQVA	

FDA Prescription Simulation Responses (<u>Aggregate Report)</u>

209 People Received Study

79 People Responded

Study Name: Norliqva

Total	18	20	10	27	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
MOLECKA	0	0	1	0	1
NOLIQVA	0	0	1	0	1
NONLIGRA	0	0	0	1	1
NONLIQVA	0	0	0	2	2
NORIGVA	0	0	1	0	1
NORLEEKVA	0	0	1	0	1
NORLEQVA	0	0	0	1	1
NORLIGLA	0	0	1	0	1
NORLIGRA	0	0	0	2	2
NORLIGUA	0	0	0	2	2
NORLIGVA	2	0	1	1	4
NORLIKVA	0	0	1	0	1
NORLIQTA	0	0	1	0	1
NORLIQUA	0	0	1	6	7
NORLIQVA	15	20	0	12	47
NORLIVKA	0	0	1	0	1
NOVLIQVA	1	0	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Norliqva **Established name:** amlodipine **Dosage form:** oral solution **Strength(s):** 1 mg/mL **Usual Dose:** 2.5 mg to 10 mg 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.	(b) (4) ***	72	Proposed proprietary name for NDA 214439 found unacceptable (OSE# 2020-41453552) on 10/13/2020. Subsequently, the sponsor submitted proposed proprietary name Norliqva*** which is the subject of this review.
2.	Norliqva***	100	This name is the subject of this review.
3.	Norlyda	72	Orthographically, both names bear different infixes (-liq- vs. -ly-) and suffixes (-va vs. -da). Phonetically, the 2nd and 3rd syllables of both names sound different: ("lik" vs. "lye", and "vah" vs. "dah") and that of Norliqva contains a hard consonant ("k") which serves to provide some differences. Although Norliqva and Norlyda are both available as single strength oral products (1 mg/mL vs. 0.35 mg) where the strength may not be specified on a prescription, the products differ in terms of dose (2.5 mg to 10 mg vs. 1 tab), and dosage form (oral solution vs. tablet); thus, the product characteristic differences provide additional differentiation if included on a prescription.

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.	Brilinta	56
2.	Minolira	55
3.	Northera	56

No.	Name	POCA Score (%)
4.	Northyx	56
5.	Norvir	56
6.	orlistat	58
7.	Starlix	56
8.	Terlivaz***	62

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:** Norliqva **Established name:** amlodipine **Dosage form:** oral solution **Strength(s):** 1 mg/mL **Usual Dose:** 2.5 mg to 10 mg 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.	Anoro Ellipta	59	This name pair has sufficient orthographic and phonetic differences.
2.	Durlaza***	56	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences. Note: Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (Panorama # (b) (4)) on April 22, 2019.
4.	Garlique	63	This name pair has sufficient orthographic and phonetic differences. Although Norliqva and Garlique are both available as single strength oral products (1 mg/mL vs 400 mg) and are administered orally once daily, the products differ in terms of dosage form (oral solution vs. enteric coated caplet) and dose (2.5 mg to 10 mg vs. 1 caplet or 400 mg); thus, the product characteristic differences provide additional differentiation if included on a prescription.
5.	Marlissa	60	This name pair has sufficient orthographic and phonetic differences.
6.	Miralax	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Norliqva **Established name:** amlodipine **Dosage form:** oral solution **Strength(s):** 1 mg/mL **Usual Dose:** 2.5 mg to 10 mg 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**
7.	Nerlynx	57	This name pair has sufficient orthographic and phonetic differences.
8.	Nolix	62	This name pair has sufficient orthographic and phonetic differences. Note: Discontinued orphenadrine product with generic equivalents available.
9.	Norflex	66	This name pair has sufficient orthographic and phonetic differences. Note: Discontinued orphenadrine product with generic equivalents available.
10.	Norlac RX	64	This name pair has sufficient orthographic and phonetic differences.
11.	Norlutate	56	This name pair has sufficient orthographic and phonetic differences.
12.	Norlutin	65	Orthographic: Norliqva contains a down stroke letter 'q' in the 6th position vs. Norlutin contains an upstroke letter 't' in the 6th position. In addition, the suffixes ('va' vs. 'tin') should help differentiate the names. Phonetic: 3rd syllables ('va' pronounced 'vah' vs. 'tin' pronounced 'teen') provide sufficient phonetic differences. Although Norliqva and Norlutin are both available as single strength oral products (1 mg/mL vs 5 mg) and may be administered orally once daily, the products differ in terms of dosage form (oral solution vs. tablet) and dose (2.5 mg to 10 mg vs 5 mg); thus, the product characteristic differences provide additional differentiation if included on a prescription.
13.	Norlyroc	59	This name has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Norliqva **Established name:** amlodipine **Dosage form:** oral solution **Strength(s):** 1 mg/mL **Usual Dose:** 2.5 mg to 10 mg 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**
14.	Nor-Qd	56	This name has sufficient orthographic and phonetic differences.
15.	Norvasc	58	This name has sufficient orthographic and phonetic differences
16.	Novolin L	57	This name has sufficient orthographic and phonetic differences
17.	Novolin R	58	This name has sufficient orthographic and phonetic differences
18.	Orbivan	56	This name pair has sufficient orthographic and phonetic differences.
19.	Orilissa	57	This name pair has sufficient orthographic and phonetic differences.
20.	Soliqua 100/33***	59	This name pair has sufficient orthographic and phonetic differences.
21.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Duralex	52
2.	Innovar	44
3.	Lanorinal	52
4.	Norepinephrine	33
5.	Nortriptyline	42
6.	Nyquil	33
7.	Ocaliva	53
8.	(b) (4) ***	54
9.	Qoliana	50
10.	Vaniqa	46

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.	(b) (4)***	57	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (OSE# (b) (4)). Subsequently, the Sponsor submitted the proposed proprietary name (b) (4)*** for NDA (b) (4) and this was also found unacceptable by DMEPA (OSE# (b) (4)).
2.	Dorflex	56	International product marketed in Brazil
3.	(b) (4)***	60	Proposed proprietary name withdrawn by the Applicant on 02/21/2019. A new proposed proprietary name for IND (b) (4) was submitted but found to be unacceptable (RCM# (b) (4) . The alternate proposed proprietary name, (b) (4)***, was submitted under NDA (b) (4) was found conditionally acceptable. However, NDA (b) (4) was withdrawn by the applicant on May 19, 2020.
4.	(b) (4)***	59	Proposed proprietary name withdrawn by the Applicant on December 12, 2018 for IND (b) (4) Product approved under the proprietary names, (b) (4) .
5.	(b) (4)***	56	Proposed proprietary name for IND 135058, which DMEPA found unacceptable (OSE# 2018-24459406, dated 8/31/2018). Orladeyo*** was later found conditionally acceptable for IND 135058 (OSE# 2018-26291674, dated 1/4/2019).
6.	(b) (4)***	66	Proposed proprietary name submitted to IND 118296 and found unacceptable by DMEPA (RCM 2017-15648818) on November 8, 2017. NDA 210868 was subsequently approved under the proprietary name Lorbrena (lorlatinib).
7.	Narvox	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Natrilix	60	International indapamide product marketed in various countries.
9.	Nelova	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
10.	(b) (4)***	58	Proposed proprietary name found unacceptable (OSE RCM # (b) (4)) on 01/16/2020. Subsequently, the proposed proprietary name (b) (4)*** was found conditionally acceptable for IND (b) (4) (OSE# (b) (4)).
11.	Norcept-E 1/35 21	55	Brand discontinued with no generic equivalents available. ANDA 071545 withdrawn FR effective 03/26/2018.
12.	Norcept-E 1/35 28	55	Brand discontinued with no generic equivalents available. ANDA 071546 withdrawn FR effective 03/26/2018.
13.	Nordox	56	International product marketed in Chile and the UK.
14.	Norel Ex	66	Discontinued phenylephrine/guaifenesin product with no generic equivalents available.
15.	Norel La	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Norgalax	64	International docusate sodium product marketed in various countries.
17.	Norlestrin 21 1/50	58	Name identified in RxNorm database. Discontinued oral contraceptive with no generic equivalents available.
18.	Norlestrin 21 2.5/50	58	Name identified in RxNorm database. Discontinued oral contraceptive with no generic equivalents available.
19.	Norlestrin 28 1/50	58	Name identified in RxNorm database. Discontinued oral contraceptive with no generic equivalents available.
20.	Normiflo	56	Discontinued norfloxacin product with no generic equivalents available.
21.	Noroxin	60	Discontinued norfloxacin product with no generic equivalents available.
22.	Norplant	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
23.	Norprolac	55	International product marketed in Europe, Canada, Turkey and South Africa.
24.	Norval	61	International product formerly marketed in the UK
25.	Norvaxs	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	orlenta	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
27.	Raplixa	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
28.	(b) (4)***	56	Proposed proprietary name for IND (b) (4) found to be unacceptable (OSE # (b) (4)). Alternative name (b) (4)*** (OSE # (b) (4)) found to be acceptable by DMEPA.

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

No.	Name	POCA Score (%)
1.	Zolinza	58
2.	Zorblisa***	61

[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

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

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:	October 13, 2020
Application Type and Number:	NDA 214439
Product Name and Strength:	(b) (4) (amlodipine) Oral Solution, 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development LLC (CMP)
Panorama #:	2020-41453552
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

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CHI-MING TU
10/13/2020 09:16:58 PM