CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213260Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 21, 2022
Application Type and Number:	NDA 213260
Product Name and Strength:	Atorvaliq (atorvastatin) suspension, 20 mg per 5 mL (4 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development LLC (CMP)
PNR ID #:	2022-1044724694
DMEPA 1 Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDCES
DMEPA 1 Team Leader:	Idalia E. Rychlik, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Atorvaliq, 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 [redacted] for this proposed proprietary name. The submitted external name study was reviewed under IND 137915 (See Section 1.1 below).[a]

1.1 REGULATORY HISTORY

CMP previously submitted the proposed name Atorvaliq for review on April 3, 2019 under IND 137915. We found the name to be conditionally acceptable on September 25, 2019.[a] However, on December 18, 2019, we amended our previous decision and found the name Atorvaliq to be unacceptable due to orthographic similarity and overlapping product characteristics with another proprietary name that was under review at the time, [redacted]).[b]

CMP resubmitted the request for proprietary name review for Atorvaliq under NDA 213260 on January 13, 2020; however, on March 12, 2020, we found the name Atorvaliq to still be unacceptable due to the risk of confusion with the same proposed proprietary name identified in our prior review ([redacted][c] Subsequently, CMP submitted the name [redacted] for review on April 13, 2020, which we found conditionally acceptable on June 12, 2020.[d] However, on October 12, 2020, we amended our decision and found the name [redacted] to be unacceptable due to spelling, orthographic similarity, phonetic similarity, and overlapping product characteristics with another proprietary name that was under review at the time, [redacted] *** [redacted][e] NDA 213260 received a complete response (CR) on October 16, 2020.

Subsequently, CMP submitted their response to the CR on August 1, 2022, and the proposed proprietary name, Atorvaliq, for review on August 4, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 4, 2022 and the labeling submission received on August 1, 2022.

- Intended Pronunciation: a tore' va leek

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[a] Fanari, M. Proprietary Name Review for Atorvaliq (IND 137915). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2019 Sep 25. PNR ID No. 2019-30533894.

[b] Gao, T. Proprietary Name Memorandum for Atorvaliq (IND 137915). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2019 Dec 18. PNR ID No. 2019-30533894-1.

[c] Fanari, M. Proprietary Name Memorandum for Atorvaliq (NDA 213260). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2020 Mar 12. PNR ID No. 2020-37123843.

[d] Fanari, M. Proprietary Name Review for [redacted] (NDA 213260). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2020 Jun 12. PNR ID No. 2020-39173472.

[e] Mena-Grillasca, C. Proprietary Name Memorandum for [redacted] (NDA 213260). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2020 Oct 13. PNR ID No. 2020-39173472-1.

- Active Ingredient: atorvastatin
- Indication of Use:

> ATORVALIQ is an HMG-CoA reductase inhibitor indicated as an adjunct therapy to diet to:
> - Reduce the risk of MI, stroke, revascularization procedures, and angina in adult patients without CHD, but with multiple risk factors (1.1).
> - Reduce the risk of MI and stroke in adult patients with type 2 diabetes without CHD, but with multiple risk factors (1.1).
> - Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in adult patients with CHD (1.1).
> - Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (1.2).
> - Reduce elevated TG in adult patients with hypertriglyceridemia and primary dysbetalipoproteinemia (1.2).
> - Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) (1.2).
> - Reduce elevated total-C, LDL-C, and apo B levels in pediatric patients, 10 years to 17 years of age, with heterozygous familial hypercholesterolemia (HeFH) after failing an adequate trial of diet therapy (1.2).

- Route of Administration: oral
- Dosage Form: suspension
- Strength: 20 mg per 5 mL (4 mg/mL)
- Dose and Frequency: 10 mg to 80 mg once daily.
- How Supplied: bottle containing 150 mL
- Storage: Store at controlled room temperature 20 - 25°C (68 - 77°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Atorvaliq would not misbrand the proposed product on August 24, 2022. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Atorvaliq. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Atorvaliq.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

CMP indicated in their submission that the proposed proprietary name, Atorvaliq, is "derived from the established name" atorvastatin. 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 can contribute to medication error.

Of note, our review of the proposed name noted that the name contained the letters 'liq', which could allude to the dosage form. However, considering that this product is an oral suspension, the inclusion of the letters 'liq' is not misleading.

2.2.3 Comments from Other Review Disciplines at Initial Review

On September 7, 2022, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) did not forward any comments or concerns relating to Atorvaliq at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-nine (99) practitioners participated in DMEPA's prescription studies for Atorvaliq. 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[g] identified 106 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review (PNR ID# 2019-30533894).[h] We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 17 names not previously analyzed and these names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the 17 names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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[f] USAN stem search conducted on August 11, 2022.

[g] POCA search conducted on August 11, 2022 in version 4.4.

[h] Fanari, M. Proprietary Name Review for Atorvaliq (IND 137915). Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2019 Sep 25. PNR ID No. 2019-30533894.

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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	17
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 17 names contained in Table 1 determined none of the names will pose a risk for confusion with Atorvaliq as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On October 21, 2022, DMEPA 1 communicated our determination to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO).

3 CONCLUSION

The proposed proprietary name, Atorvaliq, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO CMP DEVELOPMENT LLC

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

If any of the proposed product characteristics as stated in your submission, received on August 4, 2022, 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. [i]

[i] 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[j]. 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

[j] 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.

   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.

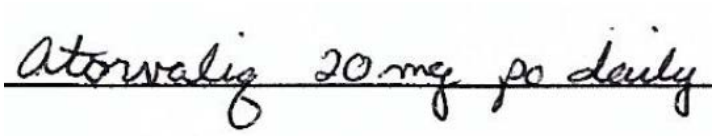
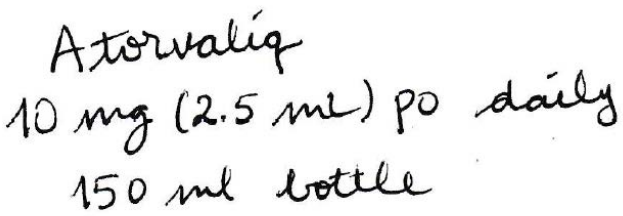
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Atorvaliq Study (Conducted on August 19, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Atorvaliq Take 10 mg or 2.5 mL by mouth daily Dispense 150 mL bottle
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Atorvaliq	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Atorvaliq
As of Date 9/15/2022

265 People Received Study
99 People Responded

Study Name: Atorvaliq

Total	25	26	21	27	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
ACTORVALIQ	0	0	1	0	1
ACTORVOLIK	0	0	1	0	1
ATO VELIC	0	0	1	0	1
ATORBALIQ	0	0	1	0	1
ATORBOLIQUE	0	0	1	0	1
ATORVALEET	0	0	1	0	1
ATORVALIK	0	0	2	0	2
ATORVALIQ	25	26	8	26	85
ATORVALIQ 10 MG (2.5ML(	0	0	0	1	1
ATORVALIQUE	0	0	3	0	3
ATORVOLIQ	0	0	1	0	1
ATROVOLIQUE	0	0	1	0	1

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

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 – N/A

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:** Atorvaliq **Established name:** atorvastatin **Dosage form:** suspension **Strength(s):** 20 mg per 5 mL (4 mg/mL) **Usual Dose:** 10 mg to 80 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.	Toradol Im	66	This name pair has sufficient orthographic and phonetic differences.
2.	Tadliq	60	This name pair has sufficient orthographic and phonetic differences.
3.	Norliqva	58	This name pair has sufficient orthographic and phonetic differences.
4.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.
5.	Toradol Iv/Im	57	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.	(b) (4)	66 (	Proposed proprietary name for IND 104187 found unacceptable by DMEPA due to the risk for confusion with another proposed proprietary name that was also under review at that time, Atorvaliq (OSE# 2019-32766457 dated 12/18/2019). Subsequently, NDA 214622 was approved on March 28, 2021, under the proprietary name Truseltiq.

No.	Name	POCA Score (%)	Failure preventions
2.	(b) (4) ***	66	(b) (4)
3.	(b) (4) ***	64	(b) (4)
4.	(b) (4)	64	Proposed proprietary name for NDA 213260 previously found conditionally acceptable (OSE # 2020-39173472 dated 6/19/2020) after denial of Atorvaliq*** (OSE# 2020-37123843 dated 3/12/2020). Subsequently, the proposed proprietary name (b) (4) for NDA 213260 was also found unacceptable by DMEPA (OSE# 2020-39173472-1 dated 10/13/2020). NDA 213260 received a complete response 10/16/2020. Response to complete response submitted on 8/4/2022 included request to review Atorvaliq, which is the subject of this name review.
5.	Cardalis	62	Veterinary product.
6.	(b) (4) ***	60	Proposed proprietary name for ANDA 206084 found unacceptable by DMEPA (OSE Review #2020-38576303 dated 07/30/2020). ANDA 206084 approved under the proprietary name Lypqozet.
7.	(b) (4) ***	56	(b) (4)
8.	Acid Violet 9	55	Product not a drug. It is a synthetic pigment used as a colorant in cosmetic formulations.

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

No.	Name	POCA Score (%)
1.	Truseltiq	60
2.	(b) (4) ***	56
3.	Etodolac	56
4.	Sotorasib	55

[k] 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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/s/

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PROPRIETARY NAME MEMORANDUM

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)

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Date of This Review:	October 13, 2020
Application Type and Number:	NDA 213260
Product Name and Strength:	(b) (4) (atorvastatin calcium) oral suspension 20 mg/5 mL (4 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development, LLC (CMP)
Panorama #:	2020-39173472-1
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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/s/

CARLOS M MENA-GRILLASCA
10/13/2020 04:46:49 PM

HINA S MEHTA
10/13/2020 08:46:37 PM

CHI-MING TU
10/13/2020 09:17:39 PM

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)

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Date of This Review:	June 12, 2020
Application Type and Number:	NDA 213260
Product Name and Strength:	(b) (4) (atorvastatin calcium) oral suspension, 20 mg/5 mL (4 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development, LLC (CMP)
Panorama #:	2020-39173472
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

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/s/

MELINA N FANARI
06/12/2020 11:37:49 AM

SEVAN H KOLEJIAN
06/12/2020 11:43:51 AM

PROPRIETARY NAME MEMORANDUM

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)

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Date of This Review:	March 12, 2020
Application Type and Number:	NDA 213260
Product Name and Strength:	Atorvaliq (atorvastatin) oral suspension, 20 mg/5 mL (4 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development, LLC
Panorama #:	2020-37123843
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA
DMEPA Deputy Director:	Irene Z. Chan, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Atorvaliq, which was found unacceptable under IND 137915 on December 18, 2019.[a] CMP Development submitted the name, Atorvaliq, under NDA 213260 for review on January 13, 2020. 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 Atorvaliq would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Atorvaliq.

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. 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 March 3, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Atorvaliq.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on March 10, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on March 10, 2019, they stated no additional concerns with the proposed proprietary name, Atorvaliq.

3 CONCLUSION

Our re-assessment determined that the proposed name, Atorvaliq, could result in medication errors due to confusion with (b) (4)***. Our evaluation of this name pair was previously discussed in the review dated December 18, 2019[a]. The rationale for the risk of confusion is described below.

Atorvaliq vs. Atruviq***

The proposed proprietary name, Atorvaliq, may be confused with another pending proposed proprietary name that is also under review, (b) (4)*** (b) (4) due to orthographic similarity and overlapping product characteristics. (b) (4)*** is indicated for

[a] Gao, T. Proprietary Name Review for Atorvaliq (IND 137915). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Dec 18. Panorama No.: 2020-30533894-1.

(b) (4)

(b) (4)

(b) (4)

Furthermore, postmarketing reports of errors involving confusion between similarly named drug products, even when indication differ. For example, name confusion has been reported between Nexavar and Nexium despite their differences in indication.[d]

Based on the totality of the information above, we find the proposed proprietary name, Atorvaliq, vulnerable to medication errors due to name confusion with (b) (4)***. Therefore, we maintain that the proposed proprietary name, Atorvaliq, is unacceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

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[b] POCA search conducted on October 25, 2019 in version 4.3.

[c] Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

[d] Institute for Safe Medication Practices. 2008 Feb 28. New look-alike name pair. ISMP Med Saf Alert Acute Care or Community/Ambulatory Care. 13(4):3-4

3.1 COMMENTS TO CMP DEVELOPMENT, LLC

On December 19, 2019 we determined that your proposed proprietary name, Atorvaliq, could result in medication errors due to confusion with another product that is currently under review. We continue to maintain this determination. Therefore, the ultimate acceptability of your proposed proprietary name, Atorvaliq, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name of Atorvaliq, you will be requested to submit another name.

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.

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/s/

MELINA N FANARI
03/12/2020 01:53:16 PM

SEVAN H KOLEJIAN
03/12/2020 01:54:29 PM

IRENE Z CHAN
03/16/2020 12:03:32 PM