

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

216395Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	June 13, 2025
Application Type and Number:	NDA 216395
Product Name, Dosage Form, and Strength:	Quiofic (folic acid) oral solution, 1 mg/5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMP Development LLC (CMC)
PNR ID #:	2025-1044726377
DMEPA 2 Safety Evaluator:	Sue Black, PharmD
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Table of Contents

1	Introduction.....	3
1.1	Regulatory History	3
1.2	Product Information.....	3
2	Discussion	4
2.1	Misbranding Assessment	5
2.2	Safety Assessment	5
2.2.1	United States Adopted Names (USAN) Search	5
2.2.2	Components of the Proposed Proprietary Name	5
2.2.3	Comments from Other Review Disciplines at Initial Review.....	6
2.2.4	FDA Prescription Simulation Studies	6
2.2.5	Phonetic and Orthographic Computer Analysis (POCA) Search Results	6
2.2.6	Names Retrieved for Review Organized by Name Pair Similarity.....	6
2.2.7	Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities	6
2.2.8	Communication of DMEPA's Determination	6
3	Conclusion	6
3.1	Comments to CMP Development LLC	7
4	References	8
5	Appendices	9

1 INTRODUCTION

This review evaluates the proposed proprietary name, Quiofic, 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. CMC did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

CMC previously submitted the proposed proprietary name, (b) (4) *** under IND 144328 on July 22, 2024. However, on January 17, 2025, we found the name, (u) (4) *** unacceptable due to orthographic similarities and overlapping product characteristics with the proprietary name, (b) (4)

Thus, CMC submitted the proposed proprietary name, Quiofic, for review on April 1, 2025 under NDA 216395.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 1, 2025^b and the prescribing information received on April 21, 2025.^c

Table 1. Relevant Product Information for Quiofic	
Intended pronunciation:	kwi oh' fik
Active ingredient:	folic acid
Indication:	Treatment of megaloblastic anemias due to a deficiency of folic acid (as may be seen in tropical or non-tropical sprue) and in anemias of nutritional origin, pregnancy, infancy, or childhood
Dosage Form:	oral solution
Strength:	1 mg/5 mL
Route of administration:	Oral

^a Black, S. Proprietary Name Review for (b) (4) *** (IND 144328). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 JAN 17. PNR ID No. 2024-1044725899.

^b Proprietary Name Request (NDA 216395 and Quiofic). Farmville (NC): CMP Development LLC; 2025 APR 01. Available from: <\\CDSESUB1\EVSPROD\nda216395\0002\m1\us\1-12-other-corres\1-12-4-0-prop-name-request.pdf>.

^c Proposed prescribing information for Quiofic. Farmville (NC): CMP Development LLC; 2025 APR 21. Available from: <\\CDSESUB1\EVSPROD\nda216395\0004\m1\us\1-14-labeling\1-14-1-draft-labeling\1-14-1-3-draft-pi.pdf>.

Table 1. Relevant Product Information for Quiofic	
Dose and frequency:	Doses greater than 0.1 mg (0.5 mL) should not be used unless anemia due to vitamin B12 deficiency has been ruled out or is being adequately treated with a cobalamin. Daily doses greater than 1 mg (0.5 mL) do not enhance the hematologic effect, and most of the excess is excreted unchanged in the urine. The usual therapeutic dosage in adults and children (regardless of age) is up to 1 mg (5 mL) daily. Resistant cases may require larger doses. When clinical symptoms have subsided and the blood picture has become normal, a daily maintenance level should be used as follows: • Infants: 0.1 mg (0.5 mL) daily • Children less than 4 years: up to 0.3 mg (1.5 mL) daily • Adults and Children 4 years and older: 0.4 mg (2 mL) daily • Pregnant and Lactating Women: 0.8 mg (4 mL) daily; but never less than 0.1 mg (0.5 mL) per day Patients should be kept under close supervision and adjustment of the maintenance level made if relapse appears imminent. In the presence of alcoholism, hemolytic anemia, anticonvulsant therapy, or chronic infection, the maintenance level may need to be increased.
How Supplied:	QUIOFIC (folic acid) Oral Solution, 1 mg/5 mL is a yellow solution with a mixed berry flavor supplied in (b) (4) amber PET bottles with a child-resistant closure containing 75 mL. NDC 69499-501-75
Storage:	(b) (4) Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Listed Drug:	Folvite (folic acid) NDA 005897

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Quiofic would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Quiofic. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Quiofic.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

The proposed proprietary name, Quiofic, contains the United States Adopted Name (USAN) stem “-io-” in the infix position of the name.^d

The USAN stem “-io-” is used by the USAN Council to indicate iodine-containing contrast media products. However, we determined that the two-letter stem ‘-io-’ found in the infix of the proposed proprietary name is not distinct enough to be recognized as a USAN stem. We also note that USAN has used the stem ‘io’ in established names (e.g., vortioxetine) as well as in other USAN stems (-tioxetine). This has resulted in conflicting stems, and therefore in those instances, the stem does not support the USAN Council naming system or accurately indicate the pharmacological or chemical trait of the drug. Additionally, based on our postmarketing experience, we do not have the same safety concerns with the two-letter stems, including ‘io,’ that we have identified with three or more letter USAN stems^{e,f}. Therefore, we do not object to the inclusion of the two-letter USAN Stem ‘io,’ incorporated into the proposed proprietary name Quiofic.^g

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

CMC did not provide a derivation or intended meaning for the proposed proprietary name, Quiofic, 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 can contribute to medication errors.

^d USAN stem search conducted on May 8, 2025.

^e Institute for Safe Medication Practices. Safety briefs: Aripiprazole or rabeprazole? ISMP Med Saf Alert Acute Care. 2003;8(8):1-3.

^f Institute for Safe Medication Practices. Safety Briefs. ISMP Med Saf Alert Acute Care. 2002;7(17):1-2.

^g Guidance for Industry: Developing Proprietary Names for Human Prescription Drug Products. Guidance December 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry>.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

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

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety (90) practitioners participated in FDA's prescription simulation studies for Quiofic. 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^h identified 38 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	35
Low similarity name pair: combined match percentage score $\leq 54\%$	2

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

Our analysis of the 38 names contained in Table 2 determined none of the names will pose a risk for confusion with Quiofic as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On June 13, 2025, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Quiofic, is conditionally acceptable.

^h POCA search conducted on May 8, 2025 in version 5.12.8.

3.1 COMMENTS TO CMP DEVELOPMENT LLC

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

If any of the proposed product characteristics as stated in your submission, received on April 1, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems>.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs@FDA Glossary of Terms, available at <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or>.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. **Misbranding Assessment:** For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.ⁱ

Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

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

Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Tables 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category that cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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.

- o Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.
- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

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

concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary Safety Evaluator assigned to evaluate the proposed proprietary name is responsible for considering the collective findings and provides an overall risk assessment of the proposed proprietary name.

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq$ 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
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	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

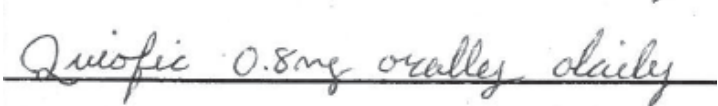
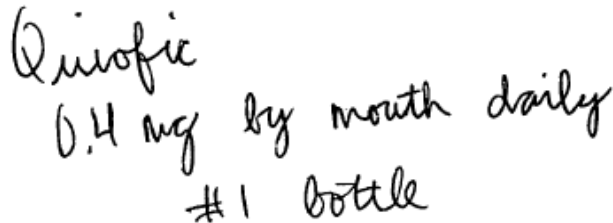
	placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	
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Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Quiofic Study (Conducted on 4/11/2025)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> 	Quiofic 0.4 mg by mouth daily Dispense 1 bottle
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Quiofic	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Quiofic					
People Received Study: 161					
People Responded: 90					
Total	25	23	22	20	90
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
GUOFIQ	0	0	1	0	1
KWAIOFIC	0	0	1	0	1
QIOFIC	0	1	0	0	1
QIOFIX	0	0	1	0	1
QIUOFIC	0	1	0	0	1
QUAIOFICK	0	0	1	0	1
QUAYOFIC	0	0	2	0	2
QUAYOFIK	0	0	1	0	1
QUIOFIC	19	21	5	20	65
QUIOFIK	0	0	1	0	1
QUIOFIX	0	0	1	0	1
QUIOFOIC	0	0	1	0	1
QUIOLIC	1	0	0	0	1

QUIOPIC	0	0	1	0	1
QUIOVIC	0	0	1	0	1
QUISFIC	5	0	0	0	5
QYIOPTIC	0	0	1	0	1
QYOPIC	0	0	1	0	1
VYOFIK	0	0	1	0	1
WYOPIC	0	0	2	0	2

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Quiofic Pronunciation: kwi oh' fik Established name: folic acid Dosage form: oral solution Strength(s): 1 mg/5 mL Dosage: 0.4 mg daily (adults and children 4 years and up), 0.8 mg daily (pregnancy and lactation), up to 0.3 mg daily (children under 4 years), 0.1 mg daily (infants); usual therapeutic dosage in adults and children regardless of age is up to 1 mg 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.	Quiofic	100	This name is the subject of this review.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

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

No.	Proposed name: Quiofic Pronunciation: kwi oh' fik Established name: folic acid Dosage form: oral solution Strength(s): 1 mg/5 mL Dosage: 0.4 mg daily (adults and children 4 years and up), 0.8 mg daily (pregnancy and lactation), up to 0.3 mg daily (children under 4 years), 0.1 mg daily (infants); usual therapeutic dosage in adults and children regardless of age is up to 1 mg 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.	Quviviq	67	Orthographically, the infixes (io vs. vi) and suffixes (fic vs. viq) differ. Specifically,

No.	Proposed name: Quiofic Pronunciation: kwi oh' fik Established name: folic acid Dosage form: oral solution Strength(s): 1 mg/5 mL Dosage: 0.4 mg daily (adults and children 4 years and up), 0.8 mg daily (pregnancy and lactation), up to 0.3 mg daily (children under 4 years), 0.1 mg daily (infants); usual therapeutic dosage in adults and children regardless of age is up to 1 mg 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
			Quiofic contains the dotted letter 'i' in the 3rd position and the rounded letter 'o' in the 4th position whereas Quviviq contains the dotted letter 'i' in the 4th position of the infix. Additionally, Quiofic contains an upstroke, and optional cross-stroke/downstroke from the letter 'f' in the 5th position and Quviviq contains the downstroke letter 'q' in the 7th position of the suffix. This provides some orthographic differences when scripted. Phonetically, the second syllable (oh' vs. VIH) also sound different when spoken. The products differ in strength (1 mg/5 mL vs. 25 mg and 50 mg) and since Quviviq is available in multiple strengths, a strength must be provided on a prescription, which may provide additional differentiation. Additionally, the names pair differ in dosage form (oral solution vs. tablet). Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Quixin	60	Orthographically, the suffixes (fic vs. xin) differ. Specifically, Quiofic contains an upstroke, and optional cross-

No.	Proposed name: Quiofic Pronunciation: kwi oh' fik Established name: folic acid Dosage form: oral solution Strength(s): 1 mg/5 mL Dosage: 0.4 mg daily (adults and children 4 years and up), 0.8 mg daily (pregnancy and lactation), up to 0.3 mg daily (children under 4 years), 0.1 mg daily (infants); usual therapeutic dosage in adults and children regardless of age is up to 1 mg 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
			stroke/downstroke from the letter 'f' in the 5th position and Quixin contains a cross-stroke letter 'x' in the 4th position. Additionally, Quiofic contains the rounded letter 'o' in the 4th position, which is absent in Quixin, providing some orthographic difference. This name pair has sufficient phonetic differences. We acknowledge both are single strength products (1 mg/5 mL vs. 0.5%), which may be omitted on a prescription, and there is no direct overlap in strength. However, the products differ in dosage form (oral solution vs. ophthalmic solution), route of administration (oral vs. ophthalmic) and frequency of administration (once daily vs. every 2 hours while awake, up to 8 times per day or every 4 hours while awake, up to 4 times per day), which may provide additional differentiation. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
3.	Quelicin	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Quiofic Pronunciation: kwi oh' fik Established name: folic acid Dosage form: oral solution Strength(s): 1 mg/5 mL Dosage: 0.4 mg daily (adults and children 4 years and up), 0.8 mg daily (pregnancy and lactation), up to 0.3 mg daily (children under 4 years), 0.1 mg daily (infants); usual therapeutic dosage in adults and children regardless of age is up to 1 mg 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
4.	Dolotic	56	This name pair has sufficient orthographic differences. Phonetically, the first syllable (kwi vs. do) and the beginning of the second syllable (oh' vs. lo) sound different when spoken. We acknowledge the name pair are single strength products (1 mg/5 mL vs. 54 mg/14 mg/mL), which may be omitted on a prescription and there is no direct overlap in strength. However, the products differ in dosage form (oral solution vs. otic solution), route of administration (oral vs. otic) and frequency of administration (once daily vs. every one to two hours until pain and congestion are relieved or three times daily for two or three days), which may provide additional differentiation. Thus, in this specific case, the risk of name confusion between this name pair is minimized.

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

No.	Name	POCA Score (%)
1.	Kaopek	44

No.	Name	POCA Score (%)
2.	Uni-Cof	44

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.	Tri-Otic	66	Veterinary product.
2.	(b) (4) ***	63	Proposed proprietary name for IND (b) (4) found to be unacceptable by DMEPA due to a conflict with a marketed product ((b) (4)). IND (b) (4) was placed on inactive status as of (b) (4) .
3.	Uni-Otic	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Q-Gesic	59	Brand discontinued with no generic equivalents available. ANDA 088740 withdrawn FR effective 01/28/1992.
5.	Liquicet	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Trioled	58	International product marketed in Thailand.
7.	Equicoxib	57	Veterinary product.
8.	Quinact	57	Brand discontinued with no generic equivalents available. ANDA 085978 withdrawn FR effective 09/11/1990 and ANDA 086099 withdrawn FR effective 08/24/1990.
9.	Equioxx	56	Veterinary Product.
10.	Equipin	55	Brand discontinued with no generic equivalents available. ANDA 086310 withdrawn FR effective 09/12/2018.
11.	(b) (4) ***	55	Proposed proprietary name for IND (b) (4) found to be conditionally acceptable ((b) (4)). The proposed proprietary name (under IND (b) (4)) was subsequently withdrawn on (b) (4) and the entire application (IND (b) (4)) was withdrawn by the Sponsor on (b) (4) . Additionally, this proposed proprietary name was submitted under IND (b) (4) on (b) (4) and subsequently withdrawn on (b) (4) IND (b) (4) withdrawn on (b) (4) .

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.	Duotic	63
2.	Clotic***	60
3.	Guaifen C	60
4.	Cyotic	59
5.	Utopic	58
6.	Co-Gesic	57
7.	Cortic	57
8.	C10-36 Olefin	56
9.	C24-28 Olefin	56
10.	C30-38 Olefin	56
11.	C30-45 Olefin	56
12.	Cleocin	56
13.	Cosuric	56
14.	Furoscix	56
15.	Guaifed	56
16.	Ticovac	56
17.	Corifact	55
18.	Ocu-Tropic	55
19.	Pediotic	55
20.	Teoptic	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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