# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 214522Orig1s000

# 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:** | April 06, 2022 |
| **Application Type and Number:** | NDA 214522 |
| **Product Name and Strength:** | Tadliq (tadalafil) Oral Suspension, 20 mg/5 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | CMP Development LLC (CMP) |
| **PNR ID #:** | 2022-1044724382 |
| **DMEPA 2 Safety Evaluator:** | Maximilian Straka, PharmD, FISMP |
| **DMEPA 2 Team Leader:** | Hina Mehta, PharmD |
| **DMEPA 2 Associate Director for Nomenclature and Labeling:** | Chi-Ming (Alice) Tu, PharmD, FISMP |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Tadliq, 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. The submitted external name study was previously reviewed under NDA 214522 on August 11, 2020 (see Section 1.1 below).

## 1.1 REGULATORY HISTORY

CMP previously submitted the proposed proprietary name, Tadliq on May 18, 2020. We found the name, Tadliq conditionally acceptable on August 11, 2020[a], however we later identified a conflict with another pending proposed proprietary name that was currently under review and found the name unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) *** under NDA 215423 on June 15, 2021.[b]

CMP submitted the name, Tadliq, for review on January 10, 2022.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 10, 2022.

- Intended Pronunciation: tad' lik
- Active Ingredient: tadalafil
- Indication of Use: The product is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability.
- Route of Administration: Oral
- Dosage Form: Oral Suspension
- Strength: 20 mg/5 mL
- Dose and Frequency: 40 mg (10 mL) once daily
- How Supplied: 150 mL bottle
- Storage: Store (b) (4)

[a] Straka, M. Proprietary Name Review for Tadliq (NDA 214522). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 11. PNR ID No. 2020-39992929.

[b] Morris, C. Tadliq Proprietary Name Review Memo (Decision Amendment) (NDA 214522). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 15. PNR ID No. 2020-1039992929-1.

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tadliq 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 Tadliq.

### 2.2 SAFETY ASSESSMENT

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

#### *2.2.1 United States Adopted Names (USAN) Search*

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

#### *2.2.2 Components of the Proposed Proprietary Name*

CMP did not provide a derivation or intended meaning for the proposed proprietary name, Tadliq, in their submission. This proprietary name is comprised of a single word that contains the letters 'liq' which may imply 'liquid'. Although we typically discourage the inclusion of medical abbreviations and product-specific attributes in proprietary names, the dosage form for the proposed product is an oral solution. In addition, the use of the 3-letter string 'liq' has been noted in other proprietary names (e.g. Eliquis, Aliqopa) and we find that it is not misleading nor can it contribute to medication error.

#### *2.2.1 Comments from Other Review Disciplines at Initial Review*

On January 26, 2022, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Tadliq at the initial phase of the review.

#### *2.2.2 FDA Name Simulation Studies*

One Hundred Seven (107) practitioners participated in DMEPA's prescription studies for Tadliq. 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.

#### *2.2.3 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

[c] USAN stem search conducted on February 18, 2022.

Our POCA search[d] identified 39 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated all of the names in our previous proprietary name review.

We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience and the change in the dosage form, which may have altered our previous conclusion regarding the acceptability of the name. We agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 2 names not previously analyzed. These names are included in Table 1 below.

### *2.2.4 Names Retrieved for Review Organized by Name Pair Similarity*

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

| Similarity Category | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 1 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 1 |

### *2.2.5 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities*

Our analysis of the 2 names contained in Table 1 determined none of the names will pose a risk for confusion with Tadliq as described in Appendices C through H.

### *2.2.6 Communication of DMEPA's Determination*

On April 06, 2022, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

## 3 CONCLUSION

The proposed proprietary name, Tadliq, is acceptable.

If you have any questions or need clarifications, please contact, OSE project manager, at.

### 3.1 COMMENTS TO CMP DEVELOPMENT LLC

[d] POCA search conducted on December 2, 2021 in version 4.4.

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

If any of the proposed product characteristics as stated in your submission, received on January 10, 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. [e]

[e] 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[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 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

[f] 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?<br>*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?<br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• 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.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• 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. |

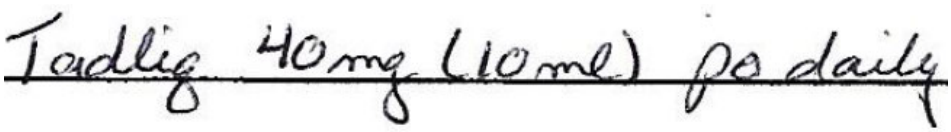
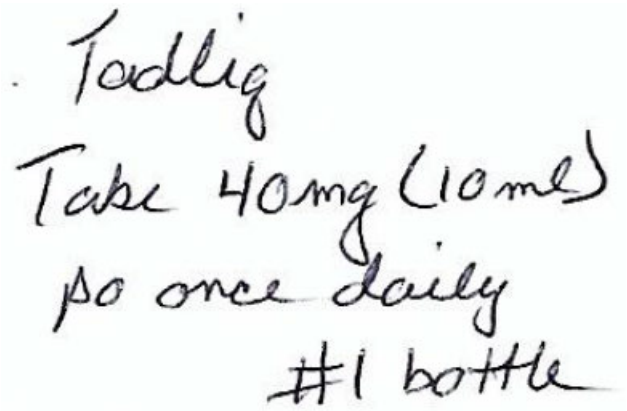
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>*FDA considers the length of names different if the names differ by two or more letters.<br>• 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?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• 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. Tadliq Study (Conducted on February 22, 2022)**

| **Handwritten Medication Order/Prescription** | **Verbal Prescription** |
|---|---|
| Medication Order:<br>  <br> | Tadliq<br>Take 40 mg or 10 mL by mouth once daily.<br>Dispense #1 Bottle |
| Outpatient Prescription:<br>  <br> | |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| Tadliq | |

**FDA Prescription Simulation Responses (Aggregate Report)**

## Study Name: Tadliq

262 People Received Study

107 People Responded

Study Name: Tadliq

| Total | 24 | 29 | 24 | 30 | |
|---|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **CPOE** | **VOICE** | **INPATIENT** | **TOTAL** |
| HABLIC | 0 | 0 | 1 | 0 | 1 |
| PADLIQ | 0 | 0 | 1 | 0 | 1 |
| PAVLICK | 0 | 0 | 1 | 0 | 1 |
| TABLEK | 0 | 0 | 1 | 0 | 1 |
| TABLEX | 0 | 0 | 1 | 0 | 1 |
| TABLIC | 0 | 0 | 3 | 0 | 3 |
| TABLICK | 0 | 0 | 3 | 0 | 3 |
| TABLIK | 0 | 0 | 4 | 0 | 4 |
| TABLIQ | 0 | 0 | 3 | 0 | 3 |
| TABLIX | 0 | 0 | 1 | 0 | 1 |
| TADLIC | 0 | 0 | 1 | 0 | 1 |
| TADLIG | 0 | 0 | 0 | 1 | 1 |
| TADLIK | 0 | 0 | 1 | 0 | 1 |
| TADLIQ | 13 | 29 | 1 | 28 | 71 |
| TAVLIK | 0 | 0 | 1 | 0 | 1 |
| TAVLIQ | 0 | 0 | 1 | 0 | 1 |
| TODLIQ | 11 | 0 | 0 | 0 | 11 |
| TORDLIQ 4O MG (10 ML) | 0 | 0 | 0 | 1 | 1 |

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

| No. | **Proposed name:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| | 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

| No. | Name | POCA Score (%) |
|---|---|---|
| | 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:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| | N/A | | |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | (b) (4) *** | 53 |

**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. | Cardalis | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| | N/A | |

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

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/s/

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HINA S MEHTA
04/06/2022 12:48:00 PM

CHI-MING TU
04/06/2022 02:48:46 PM

**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)

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

| | |
|---|---|
| **Date of This Review:** | June 15, 2021 |
| **Application Type and Number:** | NDA 214522 |
| **Product Name and Strength:** | Tadliq (tadalafil) oral suspension, 20 mg/5 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | CMP Development LLC |
| **PNR ID#:** | 2020-1039992929-1 |
| **DMEPA Safety Evaluator:** | Chad Morris, PharmD, MPH |
| **DMEPA Acting Team Leader:** | Celeste Karpow, PharmD, MPH |
| **DMEPA Deputy Director:** | Danielle Harris, PharmD |

## 1 INTRODUCTION

This memorandum is to amend the previous decision regarding the acceptability of the proposed proprietary name, Tadliq, which was found conditionally acceptable under NDA 214522 on August 11, 2020.[a] We note that a conflict exists with another similar pending proposed proprietary name that is currently under review.

## 2 DISCUSSION

DMEPA had previously reviewed the proposed proprietary name, Tadliq, under NDA 214522 and issued a ***CONDITIONALLY ACCEPTABLE*** letter for this name. Since that time, we have identified a conflict with another pending proposed proprietary name that is currently under review. The proposed name, Tadliq, could result in medication errors due to confusion with (b) (4) ***. Our evaluation of this name pair has altered our previous conclusion regarding the acceptability of the proposed proprietary name. The rationale for the risk of confusion is described below.

**Tadliq vs. (b) (4) *****

The proposed proprietary name, Tadliq, may be confused with another pending proposed proprietary name that is also under review, (b) (4) *** (tadalafil and finasteride) (NDA 215423), due to orthographic similarities and overlapping product characteristics. The proposed indication for (b) (4) *** is (b) (4)

Orthographically, Tadliq and (b) (4) *** are identical in length (6 letters) and share (b) (4) and Tadliq ends with a downstroke letter (b) (4). However, given the orthographic similarity of the rest of the name, this difference may not be sufficient to mitigate the risk of confusion.

The similarity of this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program, which calculates a combined orthographic and phonetic score of 64%, suggesting that there is moderate similarity between these names.

In addition to orthographic similarities, Tadliq and (b) (4) *** share overlapping product characteristics, which further increases the potential for wrong drug errors. Both products share an (b) (4) route of administration (oral), and frequency of administration (once daily). Additionally, there is numeric similarity in the presentation of strength and dose. Both products contain the number (b) (4) (20 mg/5 mL vs (b) (4) in the presentation of strength and both products contain the number (b) (4) (10 mL vs (b) (4) in the dose. Although the unit of measure differs between the proposed strengths (mg/mL vs mg/mg) and proposed dose (10 mL

[a] Straka, M. Proprietary Name Review for Tadliq (NDA 214522). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 11. Panorama No. 2020-399992929.

vs [redacted] the differences may not be sufficient to prevent confusion given the similarity of the names and other overlapping product characteristics.

Furthermore, since both names share the [redacted], are [redacted] letters in length, and share overlapping product characteristics, we are concerned that selection errors may occur by healthcare providers when utilizing [redacted]

We acknowledge Tadliq and [redacted]*** differ in strength and dosage form. However, we note both products are proposed to be available as a single strength and dosage form. Therefore, strength and dosage form may not be included on a prescription to help differentiate the products.

We also recognize that the products have different indications (PAH vs [redacted] however, we are concerned that this difference in indication may not prevent confusion. Despite widespread recommendations only a small percentage of medications ordered include the indication.[c]

We acknowledge our conclusion differs from that of the [redacted] external study submitted in support of the proposed proprietary name. However, the pending proprietary name, [redacted]*** is also under review and thus was not identified by the [redacted] external study.

Therefore, based on the totality of the information above, we find the proposed proprietary name, Tadliq, vulnerable to medication errors due to name confusion with [redacted]***.

We note that this decision differs from our previous decision regarding the acceptability of the proposed proprietary name, Tadliq. However, when Tadliq was previously evaluated, the proposed proprietary name, [redacted]***, was not yet submitted for review by the Agency.

### 2.1 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Cardiology and Nephrology (DCN).

## 3 CONCLUSION

The proposed proprietary name is not acceptable from a safety perspective. The proposed proprietary name, Tadliq, is vulnerable to name confusion with [redacted]***.

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

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[b] Institute for Safe Medication Practices. 2014 Jun 19. Safety briefs: Similar drug names confused. ISMP Med Saf Alert Acute Care. 19(12):1-3.

[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.

## 3.1 COMMENTS TO CMP DEVELOPMENT LLC

Your proposed name was found conditionally acceptable on August 13, 2020. Since that time, we have determined that your proposed proprietary name, Tadliq, could result in medication errors due to confusion with another product that is currently under review. Therefore, the ultimate acceptability of your proposed proprietary name, Tadliq, 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 Tadliq, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external study.

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**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.**

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/s/

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JOHN C MORRIS
06/15/2021 04:12:20 PM

CELESTE A KARPOW
06/15/2021 04:23:11 PM

DANIELLE M HARRIS
06/17/2021 07:12:16 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:** | August 11, 2020 |
| **Application Type and Number:** | NDA 214522 |
| **Product Name and Strength:** | Tadliq (tadalafil) Oral Suspension, 20 mg/5 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | CMP Development LLC (CMP) |
| **Panorama #:** | 2020-39992929 |
| **DMEPA Safety Evaluator:** | Maximilian Straka, PharmD, FISMP |
| **DMEPA Team Leader:** | Hina Mehta, PharmD |

Contents

# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Tadliq, 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 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 18, 2020.

- Intended Pronunciation: tad' lik
- Active Ingredient: tadalafil
- Indication of Use: The product is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability.
- Route of Administration: Oral
- Dosage Form: Oral Suspension
- Strength: 20 mg/5 mL
- Dose and Frequency: 40 mg (10 mL) once daily
- How Supplied: 150 mL bottle
- Storage: Store below (b) (4)

# 2 RESULTS

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

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tadliq 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 Tadliq.

## 2.2 SAFETY ASSESSMENT

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

### *2.2.1 United States Adopted Names (USAN) Search*

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

### *2.2.2 Components of the Proposed Proprietary Name*

CMP did not provide a derivation or intended meaning for the proposed proprietary name, Tadliq, in their submission. This proprietary name is comprised of a single word that contains the letters 'liq' which may imply 'liquid'. Although we typically discourage the inclusion of medical abbreviations and product-specific attributes in proprietary names, the dosage form for the proposed product is an oral solution. In addition, the use of the 3-letter string 'liq' has been noted in other proprietary names (e.g. Eliquis, Aliqopa) and we find that it is not misleading nor can it contribute to medication error.

### *2.2.3 Comments from Other Review Disciplines at Initial Review*

In response to the OSE, May 28, 2020 e-mail, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Tadliq at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

Eighty-eight (88) practitioners participated in DMEPA's prescription studies for Tadliq. 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[b] identified 48 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.

[a] USAN stem search conducted on June 4, 2020.

[b] POCA search conducted on May 27, 2020 in version 4.3.

### *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:<br>combined match percentage score ≥70% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 37 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 11 |

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

Our analysis of the 49 names contained in Table 1 determined none of the names will pose a risk for confusion with Tadliq 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 August 5, 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 August 7, 2020, they stated no additional concerns with the proposed proprietary name, Tadliq.

## 3 CONCLUSION

The proposed proprietary name, Tadliq, is acceptable.

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, Tadliq, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on May 18, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 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. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***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[d]. 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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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?<br>*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?<br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• 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.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• 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. |

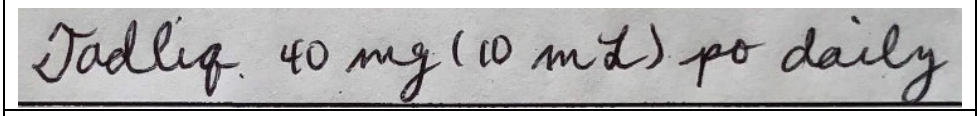
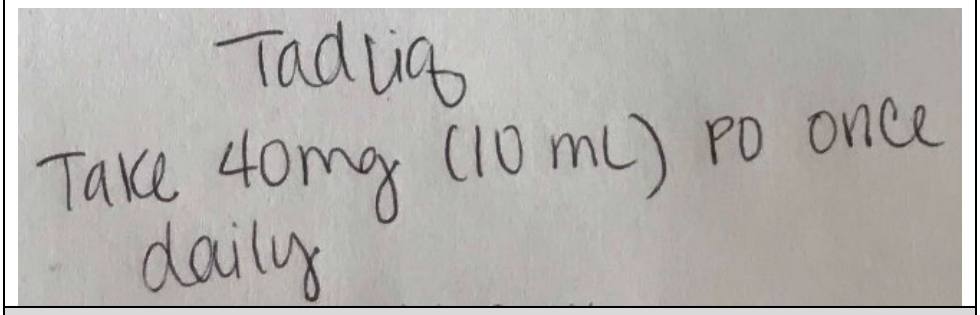
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>*FDA considers the length of names different if the names differ by two or more letters.<br>• 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?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• 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. Tadliq Study (Conducted on May 29, 2020)**

| **Handwritten Medication Order/Prescription** | **Verbal Prescription** |
|---|---|
| Medication Order:<br>  <br><br>Outpatient Prescription:<br>  <br> | Tadliq<br>Take 40 mg or 10 mL by mouth once daily.<br>Dispense # 1 bottle |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| Tadliq | |

## Study Name: Tadliq

As of Date 6/17/2020

208 People Received Study

88 People Responded

Study Name: Tadliq

| Total | 20 | 30 | 21 | 17 | |
|---|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **CPOE** | **VOICE** | **INPATIENT** | **TOTAL** |
| JADLIQ | 0 | 0 | 0 | 1 | 1 |
| KADLICK | 0 | 0 | 1 | 0 | 1 |
| PACLIQ | 0 | 0 | 1 | 0 | 1 |
| PADLIC | 0 | 0 | 2 | 0 | 2 |
| PADLICK | 0 | 0 | 9 | 0 | 9 |
| PADLIK | 0 | 0 | 4 | 0 | 4 |
| PADLIQ | 0 | 0 | 1 | 0 | 1 |
| PADLIQUE | 0 | 0 | 2 | 0 | 2 |
| PAVLIK | 0 | 0 | 1 | 0 | 1 |
| TADLIQ | 19 | 30 | 0 | 15 | 64 |
| TADUQ | 1 | 0 | 0 | 0 | 1 |
| TAGLIQ | 0 | 0 | 0 | 1 | 1 |

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

| No. | **Proposed name:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | POCA Score (%) | Orthographic and/or phonetic differences in the names sufficient to prevent confusion<br><br>Other prevention of failure mode expected to minimize the risk of confusion between these two names. |
|---|---|---|---|
| 1. | Tadliq*** | 100 | This name is the subject of this review. |

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

| No. | Name | POCA Score (%) |
|---|---|---|
| 2. | T-Diet | 56 |

**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:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | POCA Score (%) | Prevention of Failure Mode<br><br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 3. | Penlac | 54 | Phonetically, the first syllable (pen) in Penlac sounds different than the first syllable (tad) of Tadliq.<br><br>In addition to the orthographic and phonetic differences, the following non-overlapping product characteristics would help to mitigate the error when included on a prescription: Strength (8% vs. 20 mg/5 mL), Dose (Apply evenly over entire nail vs. 40 mg) and Route (topical vs. oral). |
| 4. | Satric | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 5. | Siliq | 61 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Stadol | 57 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 7. | Tabloid | 68 | The letter 'b' in the third position of Tabloid places a space between the upstroke letter 'l" in the fourth position which looks different than the back to back upstroke letters 'd' and 'l' in Tadliq. There is also an upstroke letter 'd' at the end of Tabloid, while Tadliq ends with a downstroke letter 'q'.<br><br>Phonetically, the second syllable (loid) in Tabloid sounds different than the second syllable (lik) of Tadliq. |
| 8. | Tadalafil | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | Talc | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 10. | Talicia | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 11. | (b) (4) *** | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 12. | Thatzit | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 13. | Tiadylt | 66 | This name pair has sufficient orthographic and phonetic differences. |
| 14. | Ticlid | 67 | The upstroke letter 'd' in the third position of Tadliq as well as the downstroke letter 'q' in the sixth position compared to the upstroke letter 'd' in the sixth position of Ticlid provide some orthographic difference.<br><br>Phonetically, the first and second syllables in Tadliq (tad' lik) do not sound like the first and second syllables in Ticlid (tik lid).<br><br>In addition to the orthographic and phonetic differences, the following non-overlapping product characteristics would help to mitigate |

| No. | **Proposed name:** Tadliq<br>**Established name:** tadalafil<br>**Dosage form:** Oral Suspension<br>**Strength(s):** 20 mg/5 mL<br>**Usual Dose:** 40 mg (10 mL) once daily | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| | | | the error when included on a prescription: Dose and frequency (40 mg (10 mL) once daily vs. 250 mg twice daily).<br><br>In addition, the brand name, Ticlid, for NDA 019979 was withdrawn FR Effective 7/8/2011. |
| 15. | Titralac | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 16. | Tivdak*** | 58 | 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 (%) |
|---|---|---|
| 17. | Benziq | 52 |
| 18. | Diltia | 51 |
| 19. | D-Tal | 48 |
| 20. | Etodolac | 54 |
| 21. | P Bloc | 44 |
| 22. | Pen-Vee K | 37 |
| 23. | Qinlock*** | 54 |
| 24. | Tanac Liquid | 53 |
| 25. | Vitadil 2A | 54 |
| 26. | Vitadil 5A | 54 |

**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 |
|---|---|---|---|
| 27. | (b) (4)*** | 60 | Proposed proprietary name for IND 122708 found unacceptable by DMEPA (OSE# 2017-13080912). IND is active and no new names have been submitted. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 28. | (b) (4) *** | 58 | Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (OSE# (b) (4)). The proposed proprietary name (b) (4) *** was granted conditional approval under NDA (b) (4) |
| 29. | (b) (4) *** | 61 | Proposed proprietary name for IND 110077 found unacceptable by DMEPA (OSE# 2019-29976610). Product approved under proprietary name QWO under BLA 761146 on July 6, 2020. |
| 30. | Talwin | 58 | Brand discontinued with no generic equivalents available as per RedBook. |
| 31. | Talwin 50 | 58 | Brand discontinued with no generic equivalents available as per RedBook. |
| 32. | Teslac | 62 | Brand discontinued with no generic equivalents available. NDA 016118 withdrawn FR effective 07/08/2011. NDA 016119 withdrawn FR effective 08/20/2010. |
| 33. | Tiadilon | 58 | International product formerly marketed in France. |
| 34. | Tilade | 58 | Brand discontinued with no generic equivalents available as per RedBook. |
| 35. | Ti-Plex | 55 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 36. | Adalat | 62 |
| 37. | Betalin 12 | 56 |
| 38. | Cotellic | 56 |
| 39. | Deltalin | 55 |
| 40. | Deplin | 57 |
| 41. | Etodalac | 56 |
| 42. | Kaitlib*** | 58 |
| 43. | Kalliga | 55 |
| 44. | Metaglip | 56 |

[e] 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

| No. | Name | POCA Score (%) |
|---|---|---|
| 45. | Q-Bid La | 56 |
| 46. | Salic-2 | 62 |
| 47. | Starlix | 57 |
| 48. | Xalix | 56 |
| 49. | Xtandi | 56 |

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/s/

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