CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210795Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	February 22, 2018
Application Type and Number:	NDA 210795
Product Name and Strength:	Krintafel (Tafenoquine) Tablets, 150 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	GlaxoSmithKline Intellectal Property Development, Ltd. England
Panorama #:	2017-19475316
DMEPA Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Krintafel, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study (gap analysis), conducted by [redacted] (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Krintafel on November 25, 2014. We found the name, Krintafel conditionally acceptable under IND 101471 on February 2, 2015.[a]

The Applicant again submitted the name, Krintafel, for review on December 6, 2017 as part of their NDA submission. We note that all product characteristics remain the same as the November 25, 2014 submission.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 6, 2017 proprietary name submission.

- Intended Pronunciation: krin' ta fel
- Active Ingredient: tafenoquine
- Indication of Use: prevention of relapse of *Plasmodium vivax* malaria in patients aged 16 years and older.
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 150 mg
- Dose and Frequency: The recommended dose in adults and adolescents (aged 16 years or older) is a single dose of 300 mg administered as two 150 mg Kritafel tablets coadministered on the first or second day of chloroquine administration.
- How Supplied:
    - Bottle of 30 tablets with child-resistant closure
    - Unit Dose Pack of 2 tablets in a bottle
- Storage: Store at 20°C to 25°C (68°F to 77°F). Temperature excursions are permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

  Store in the original package to protect from moisture. Keep the bottle tightly closed and do not remove the desiccant.

[a] Sheppard, J. Proprietary Name Review for Krintafel (IND 101471). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 FEB 02. Panorama No. 2014-44155.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 19, 2017 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety practitioners participated in DMEPA's prescription studies. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 190 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.

[b] USAN stem search conducted on December 15, 2017.

[c] POCA search conducted on December 15, 2017 in version 4.2.

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 the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	172
Low similarity name pair: combined match percentage score ≤54%	40

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

Our analysis of the 215 names contained in Table 1 determined none of the names will pose a risk for confusion 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 Anti-Infective Products (DAIP) via e-mail on February 20, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on February 22, 2018, they stated no additional concerns with the proposed proprietary name, Krintafel.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ameet Joshi, OSE project manager, at 301-796-6345.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 6, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)

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.

3. Electronic Drug Registration and Listing System (eDRLS) database

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

[d] National Coordinating Council for Medication Error Reporting and Prevention. 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[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

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

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.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

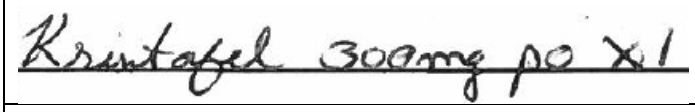
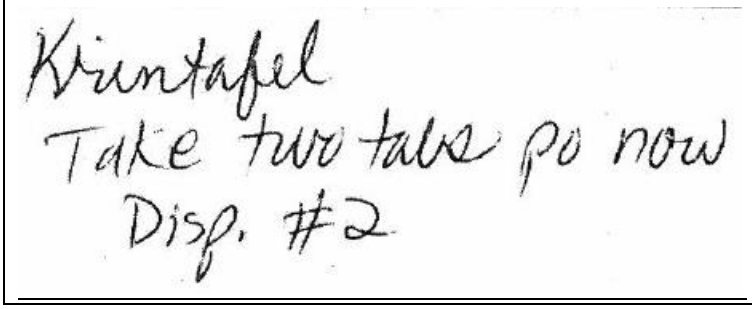
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Krintafel Study (Conducted on December 15, 2017)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Krintafel Take two tablets by mouth now. Dispense #2
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

294 People Received Study
90 People Responded

Study Name: Krintafel

Total	31	30	29	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CRENTAFEL	0	1	0	1
CRETOFEL	0	1	0	1
CRINTAFEL	0	5	0	5
CRINTAFELL	0	1	0	1
CRINTEFEL	0	1	0	1
CRINTEZELLE	0	1	0	1
CRINTIFEL	0	2	0	2
CRINTOFEL	0	1	0	1
CRIPTAFEL	0	1	0	1
CRIPTOFEL	0	2	0	2
CRIPTOFELL	0	1	0	1
CRIPTOFIL	0	1	0	1
CRITAPHIL	0	1	0	1
CRITAVEIL	0	1	0	1
KREINTAFEL	1	0	0	1
KRINTACEL	0	1	0	1
KRINTAFED	0	0	1	1
KRINTAFEL	28	2	27	57
KRINTAFELL	0	2	0	2
KRINTATHEL	1	0	0	1
KRINTEPHEL	0	1	0	1
KRINTEZEL	0	1	0	1
KRINTOFEL	0	0	1	1
KRITAFEL	0	1	0	1
KRUNTAFEL	1	0	0	1
PRINTAFELL	0	1	0	1
PRINTEFELL	0	1	0	1

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

No.	**Proposed name:** Krintafel **Established name:** tafenoquine **Dosage form:** tablet **Strength(s):** 150 mg **Usual Dose:** 300 mg administered as two 150 mg tablets taken together once	**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.	Krintafel***	100	Name is the subject of this review.
2.	Trental	70	The brand name, Trental, is no longer available, however generics remain. The beginning letters (K- vs. T-) and infixes (-intaf- vs -ent-) of this name pair (Krintafel vs. Trental) have sufficient orthographic differences. The first syllable (Krin vs. Tren) of this name pair (Krintafel vs. Trental) sound different, and Krintafel contains an extra syllable. There is no dose overlap between these products (Krintafel will be dosed as 2 tablets one time vs. Trental which is dosed as 1 tablet twice daily after meals on a continuous basis).
3.	Tri-Nasal	72	Brand discontinued with no generic equivalent available.

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

No.	Name	POCA Score (%)
1.	Remifentanil	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:** Krintafel **Established name:** tafenoquine **Dosage form:** tablet **Strength(s):** 150 mg **Usual Dose:** 300 mg administered as two 150 mg tablets taken together once	**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.	Afrin Nasal	66	This name pair has sufficient orthographic and phonetic differences.
2.	Alfentanil	56	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
4.	Clindagel	64	This name pair has sufficient orthographic and phonetic differences.
5.	Dentagel	63	This name pair has sufficient orthographic and phonetic differences.
6.	Fentanyl	59	This name pair has sufficient orthographic and phonetic differences.
7.	Fentanyl-100	59	This name pair has sufficient orthographic and phonetic differences.
8.	Fentanyl-12	59	This name pair has sufficient orthographic and phonetic differences.
9.	Fentanyl-25	59	This name pair has sufficient orthographic and phonetic differences.
10.	Fentanyl-37	59	This name pair has sufficient orthographic and phonetic differences.
11.	Fentanyl-50	59	This name pair has sufficient orthographic and phonetic differences.
12.	Fentanyl-62	59	This name pair has sufficient orthographic and phonetic differences.
13.	Fentanyl-75	59	This name pair has sufficient orthographic and phonetic differences.
14.	Fentanyl-87	59	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences.
16.	Gentafair	59	This name pair has sufficient orthographic and phonetic differences.
17.	Gentasol	60	This name pair has sufficient orthographic and phonetic differences.
18.	(b) (4)***	66	This name pair has sufficient orthographic and phonetic differences.
19.	Green-Tussin	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Krintafel **Established name:** tafenoquine **Dosage form:** tablet **Strength(s):** 150 mg **Usual Dose:** 300 mg administered as two 150 mg tablets taken together once	**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**
20.	Infantaire	50	This name pair has sufficient orthographic and phonetic differences.
21.	Injectafer	57	This name pair has sufficient orthographic and phonetic differences.
22.	Intal	54	This name pair has sufficient orthographic and phonetic differences.
23.	Integra F	50	This name pair has sufficient orthographic and phonetic differences.
24.	Interferon Alfa-2A	45	This name pair has sufficient orthographic and phonetic differences.
25.	Interferon Alfa-N3	45	This name pair has sufficient orthographic and phonetic differences.
26.	Introvale	58	This name pair has sufficient orthographic and phonetic differences.
27.	Karbinal	60	This name pair has sufficient orthographic and phonetic differences.
28.	Karbinal ER	60	This name pair has sufficient orthographic and phonetic differences.
29.	Kera Nail	66	This name pair has sufficient orthographic and phonetic differences.
30.	Kerasal AL	57	This name pair has sufficient orthographic and phonetic differences.
31.	Ketotifen	56	This name pair has sufficient orthographic and phonetic differences.
32.	(b) (4) ***	61	This name pair has sufficient orthographic and phonetic differences.
33.	Kristalose	60	This name pair has sufficient orthographic and phonetic differences.
34.	Larin 24 Fe	53	This name pair has sufficient orthographic and phonetic differences.
35.	Larin Fe 1.5/30	53	This name pair has sufficient orthographic and phonetic differences.
36.	Larin Fe 1/20	53	This name pair has sufficient orthographic and phonetic differences.
37.	Nafarelin	48	This name pair has sufficient orthographic and phonetic differences.
38.	Pentacel	68	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Krintafel **Established name:** tafenoquine **Dosage form:** tablet **Strength(s):** 150 mg **Usual Dose:** 300 mg administered as two 150 mg tablets taken together once	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**
39.	Principen	58	This name pair has sufficient orthographic and phonetic differences.
40.	Principen '250'	58	This name pair has sufficient orthographic and phonetic differences.
41.	Principen '500'	58	This name pair has sufficient orthographic and phonetic differences.
42.	Prinivil	60	This name pair has sufficient orthographic and phonetic differences.
43.	Purinethol	58	This name pair has sufficient orthographic and phonetic differences.
44.	Rhinatate	54	This name pair has sufficient orthographic and phonetic differences.
45.	Ridafed	56	This name pair has sufficient orthographic and phonetic differences.
46.	Ritalin	54	This name pair has sufficient orthographic and phonetic differences.
47.	Sprintec	55	This name pair has sufficient orthographic and phonetic differences.
48.	Sufentanil	57	This name pair has sufficient orthographic and phonetic differences.
49.	Terbinafine	56	This name pair has sufficient orthographic and phonetic differences.
50.	Tirosint-Sol	56	This name pair has sufficient orthographic and phonetic differences.
51.	Tranzarel	69	This name pair has sufficient orthographic and phonetic differences.
52.	Triafed	59	This name pair has sufficient orthographic and phonetic differences.
53.	Trinessa	57	This name pair has sufficient orthographic and phonetic differences.
54.	Trintellix	64	This name pair has sufficient orthographic and phonetic differences.
55.	Triphasil-28	62	This name pair has sufficient orthographic and phonetic differences.
56.	Triptifed	66	This name pair has sufficient orthographic and phonetic differences.
57.	Xantofyl	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 (%)
1.	Afirmelle	42
2.	Aptensio XR	36
3.	Aristogel	54
4.	Clorotekal	52
5.	Dexilant Solutab	36
6.	Elepsia XR	33
7.	Epaned	28
8.	Epanova	29
9.	Evotaz	25
10.	Genvoya	26
11.	Inflectra	44
12.	Kaitlib Fe	50
13.	Kengreal	50
14.	Ketozole	46
15.	Logiilia	26
16.	Nexesta Fe	46
17.	Prezcobix	38
18.	Qbrelis	37
19.	Quadracel	54
20.	Rayaldee	30
21.	Savaysa	19
22.	Tybost	20
23.	Zejula	22
24.	Zykadia	30

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.	Akrinol	58	Brand discontinued with no generic equivalent available. (b) (4)
2.	Bentasil	64	International product formerly marketed in Canada.

No.	Name	POCA Score (%)	Failure preventions
3.	Brintellix	60	This proprietary name, Brintellix, has been discontinued and the product is now marketed in the United States under the new name Trintellix (vortioxetine). On May 2, 2016, FDA announced it approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug Trintellix became available starting in June 2016.
4.	Bronkosol	55	Brand discontinued with no generic equivalent available. (b) (4)
5.	Clintabs	57	Veterinary product.
6.	Crantex ER	64	Brand discontinued with no generic equivalent available.
7.	Drontal	61	Veterinary product.
8.	(b) (4) ***	52	(b) (4)
9.	Ferric Nitrate	49	Product is not a drug. It is a chemical compound that appears as violet crystals and is soluble in water and alcohol. Ferric nitrate is a strong oxidant and irritant used by jewelers and metalsmiths to etch silver and silver alloys.
10.	Gantanol	56	Brand discontinued with no generic equivalent available. (b) (4)
11.	Histafed LA	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Interferon Alfa-N1	45	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Iprindole	59	International product formerly marketed in Ireland and the United Kingdom under the brand name Prondol.
14.	Kentace	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
15.	Kentiazem	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Kentovace	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Ketaflo	60	Veterinary product.
18.	Ketovail	55	International product marketed in the United Kingdom.
19.	Kraftobese	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Kraftpleg	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Kronofed-A	60	Brand discontinued with no generic equivalent available.
22.	Mantadil	56	Brand discontinued with no generic equivalent available.
23.	Mintezol	58	Brand discontinued with no generic equivalent available.
24.	Pentacef	58	Brand discontinued with no generic equivalent available. (b) (4)
25.	Pentasol	61	Veterinary product.
26.	Prantal	64	Brand discontinued with no generic equivalent available. (b) (4)
27.	Prednesol	60	International product marketed in Ireland. International product formerly marketed in the United Kingdom.
28.	Prednisol	58	Brand discontinued with no generic equivalent available.
29.	Principen '125'	58	Brand discontinued with no generic equivalent available. (b) (4)
30.	Prolintane	57	This is the established name of an international product (Catorid, Katovit, Katovit N, Promotil, and Villescon) formerly marketed in Belgium, South Africa, Australia, Germany, Switzerland, Spain, France, and the United Kingdom.
31.	Rentamine	57	Brand discontinued with no generic equivalent available.

No.	Name	POCA Score (%)	Failure preventions
32.	Retin-A Forte	53	International product marketed in Mexico.
33.	Rimafen	58	International product marketed in the United Kingdom.
34.	Rinate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Rinfabate	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	Trancopal	66	Brand discontinued with no generic equivalent available. (b) (4)
37.	Trinalin	60	Brand discontinued with no generic equivalent available. (b) (4)
38.	Tri-Nefrin	60	Product withdrawn from the market due to safety concerns (contained phenylpropanolamine). No generics exist.
39.	Trintex	64	Product withdrawn from the market due to safety concerns (contained phenylpropanolamine). No generics exist.
40.	Triphasil-21	62	Brand discontinued with no generic equivalent available.

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

No.	Name	POCA Score (%)
1.	4-Terpineol, (+)-	56
2.	Atrovent Nasal	56
3.	Brevital	58
4.	Brian Care	56
5.	Carticel	62
6.	China-Gel	58
7.	Clindacin	56
8.	Clindacure	58
9.	Clinda-Derm	56

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

No.	Name	POCA Score (%)
10.	Clindamed	56
11.	Clinitar	58
12.	Contraflam	56
13.	Crantex	60
14.	Crantex La	66
15.	Crystapen	58
16.	Crytselle	58
17.	Daptacel	55
18.	Dritail	61
19.	Entrocel	55
20.	Farbital	55
21.	Farnesal	58
22.	Farnesol	56
23.	Fer-In-Sol	56
24.	Frenadol	58
25.	Genteal	55
26.	Granisol	57
27.	Lantrisul	55
28.	Lentizol	55
29.	Morantel	58
30.	Panafil	57
31.	Pentothal	60
32.	Pentoxil	56
33.	Perampanel	58
34.	Pramegel	55
35.	Praziquantel	55
36.	Prednoral	57
37.	Pretz Nasal	58
38.	Priadel	56
39.	Primabalt	56
40.	Pronestyl	56
41.	Proventil	56
42.	Pur-In Neutral	60
43.	Pyrantel	62
44.	Quinapril	56
45.	Rectagel	61
46.	Rectasol	58
47.	Renagel	60
48.	Rifater	56
49.	Rimiterol	58
50.	Ritalin La	56
51.	Ritifed	58
52.	Sanafitil	57

No.	Name	POCA Score (%)
53.	Serentil	60
54.	Sildenafil	56
55.	Tandearil	58
56.	Tanderil	60
57.	Tensopril	55
58.	Terpineol	56
59.	Tormentil	58
60.	Trandate	55
61.	Transanosil	60
62.	Trans-Ver-Sal	58
63.	Tranxene	56
64.	Trapidil	55
65.	(b) (4) ***	56
66.	Trexall	56
67.	Triam-Forte	56
68.	Triavil	58
69.	Triavil 2-10	58
70.	Triavil 2-25	58
71.	Triavil 4-10	58
72.	Triavil 4-25	58
73.	Triavil 4-50	58
74.	Tricosal	60
75.	Tridesilon	56
76.	Trientine	58
77.	Tri-Estarylla	55
78.	Triflusal	59
79.	Trileptal	62
80.	Triptorelin	56
81.	Trisofed	56
82.	Tri-Statin	60
83.	Trital Sr	60
84.	Tri-Tannate	58
85.	Trituss Er	56
86.	Tropicacyl	56
87.	Tyzine Nasal	56
88.	Vardenafil	60
89.	Vilanterol	56
90.	Virbantel	58

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/s/

DEBORAH E MYERS
02/22/2018

OTTO L TOWNSEND
02/23/2018