CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214622Orig1s000

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:	December 23, 2020
Application Type and Number:	NDA 214622
Product Name and Strength:	Truseltiq (infigratinib) Capsules, 25 mg and 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	QED Therapeutics (QED)
Panorama #:	2020-43182613
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Ashleigh Lowery, PharmD, BCCCP

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

QED previously submitted the proposed proprietary name, (b) (4)***, on June 27, 2019 with amendments received on November 25, 2019 and November 27, 2019. However, we found the name, (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proposed proprietary name, (b) (4)***, under IND 104187 on December 18, 2019.[a]

QED then submitted the proposed proprietary name, (b) (4)*** on February 11, 2020. However, we found the name, (b) (4)*** unacceptable due to misbranding concerns under IND 104187 on April 20, 2020.[b]

Subsequently, QED submitted the name, (b) (4)*** for review on Jun 11, 2020. However, on September 11, 2020, we found the proposed proprietary name, (b) (4)*** unacceptable under IND 104187[c] due to its vulnerability to name confusion with the currently marketed product, (b) (4).

Thus, QED submitted the name, Truseltiq, for review on September 30, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 30, 2020 and amended on December 17, 2020.

- Intended Pronunciation: tru 'sel tik
- Active Ingredient: infigratinib
- Indication of Use: Treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or other rearrangements
- Route of Administration: Oral
- Dosage Form: Capsules
- Strength: 25 mg and 100 mg

---

[a] Straka, M. Proprietary Name Review for (b) (4) (IND 104187). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 DEC 18. Panorama No. 2019-32766457.

[b] Thomas, S. Proprietary Name Review for (b) (4) (IND 104187). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 20. Panorama No. 2020-37800151.

[c] Thomas, S. Proprietary Name Review for (b) (4) (IND 104187). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 SEP 11. Panorama No. 2020-40619311

- Dose and Frequency:
    - Usual dose: 125 mg (administered as one 100 mg capsule plus one 25 mg capsule) orally once daily on days 1-21 of each 28-day cycle, at least 1 hour before or 2 hours after a meal in the fasted state
        - 1st dose reduction: 100 mg (one 100 mg capsule)
        - 2nd dose reduction: 75 mg (three 25 mg capsules)
        - 3rd dose reduction: 50 mg (two 25 mg capsules)
- How Supplied: 21-day dose pack configurations as follows, with daily dose to be taken identified in the blister packs as Day 1, Day 2, Day 3, etc.:
    - Blister pack for 125 mg daily dose containing 21 x 100 mg capsules and 21 x 25 mg capsules
    - Blister pack for 100 mg daily dose containing 21 x 100 mg capsules
    - Blister pack for 75 mg daily dose containing 63 x 25 mg capsules
    - Blister pack for 50 mg daily dose containing 42 x 25 mg capsules
- Storage: Room Temperature

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Truseltiq would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 3 (DO3) concurred with the findings of OPDP's assessment for Truseltiq.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

QED did not provide a derivation or intended meaning for the proposed proprietary name, Truseltiq, 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.

[d] USAN stem search conducted on October 20, 2020.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 16, 2020 e-mail, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Truseltiq at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-nine practitioners participated in DMEPA's prescription studies for Truseltiq. We note that one participant from the CPOE portion of the study entered an incorrect sequence of letters, 'try' instead of 'tru', when searching for the study name, which generated a pick list that did not contain Truseltiq. The participant then incorrectly selected the name Trysul when searching the drug name using the first three letters. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk.

Further, Trysul is not likely to be confused with Truseltiq because there is no overlap of product characteristics with this name pair. Trysul is a proprietary name for a triple sulfa (sulfathiazole, sulfacetamide, sulfabenzamide) vaginal cream which is deactivated per RedBook with no generic equivalent available. Because the combined phonetic and orthographic score between the name pair is 54%, we include Trysul in Appendix F for our evaluation.

The remaining 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[e] identified 133 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	130
Low similarity name pair: combined match percentage score ≤54%	3

[e] POCA search conducted on October 20, 2020 in version 4.4.

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

Our analysis of the 134 names contained in Table 1 determined none of the names will pose a risk for confusion with Truseltiq 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 Oncology 3 (DO3) via e-mail on December 23, 2020.

3 CONCLUSION

The proposed proprietary name, Truseltiq, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO QED THERAPEUTICS

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

If any of the proposed product characteristics as stated in your submission, received on September 30, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

[f] 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[g]. 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

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

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

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

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

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

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

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

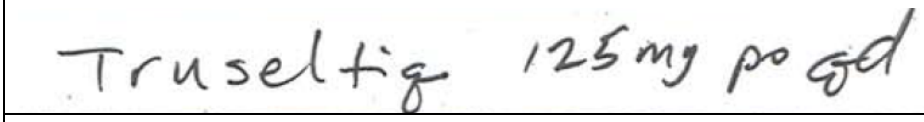
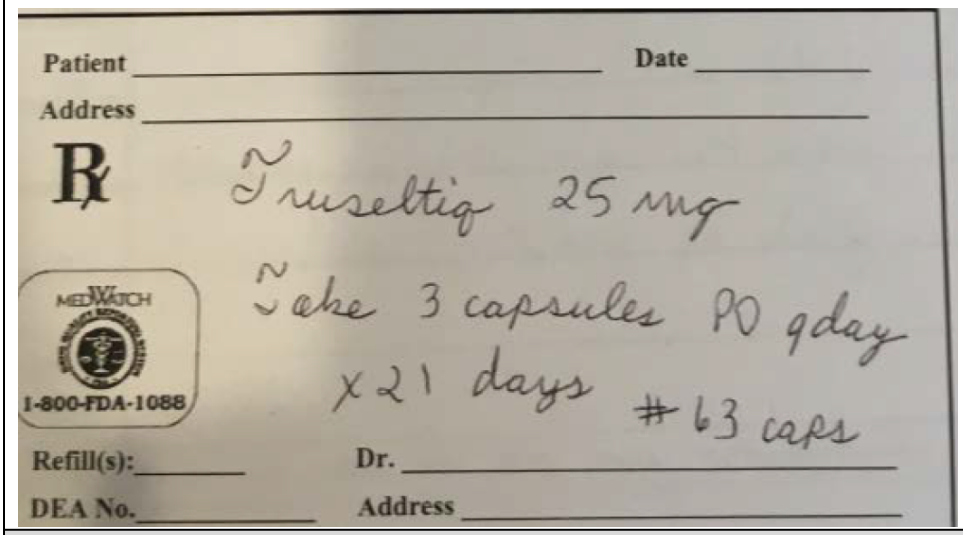
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Truseltiq Study (Conducted on October 27, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Truseltiq	Truseltiq 25 mg Take 3 capsules by mouth daily for 21 days Dispense 63 capsules

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Truseltiq

As of Date 11/16/2020

209 People Received Study

89 People Responded

Study Name: Truseltiq

Total	23	19	30	17	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
CUSELTIC	0	0	1	0	1
TOSELTIC 25 MG	0	0	1	0	1
TRUCEKTIC	0	0	1	0	1
TRUCELTIC	0	0	11	0	11
TRUCELTIQ	0	0	2	0	2
TRUCELTIX	0	0	1	0	1
TRUCELZIC	0	0	1	0	1
TRUSELTEC	0	0	2	0	2
TRUSELTIC	0	0	5	0	5
TRUSELTIG	1	0	0	0	1
TRUSELTIK	0	0	2	0	2
TRUSELTIQ	21	18	2	16	57
TRUSELTLIQ	1	0	0	0	1
TRUZELTIC	0	0	1	0	1
TRYSUL	0	1	0	0	1
TUSELTIQ	0	0	0	1	1

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

No.	**Proposed name:** Truseltiq **Established name:** infigratinib **Dosage form:** Capsules **Strength(s):** 25 mg and 100 mg **Usual Dose:** 50 mg, 75 mg, 100 mg, or 125 mg orally once daily on days 1-21 of each 28-day cycle	**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.	Truseltiq	100	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 (%)
1.	Ferriseltz	66
2.	Incruse Ellipta	56
3.	Lutrepulse Kit	57
4.	Strensiq	60
5.	Stress Liquid	63
6.	Tecentriq	61
7.	Tirosint	56
8.	Trelstar	58
9.	Tretin X	58
10.	Treximet	56
11.	Tri Vent Hc	55
12.	Tribulus	58
13.	Triesence	56
14.	Trifed C	55
15.	Triferic	62
16.	Trifexis	61
17.	Tri-Legest 21	55
18.	Trilipix	58
19.	Trilisate	60
20.	Trilyte	56
21.	Tri-Otic	55
22.	Triseptin	68
23.	Tri-Sprintec	56
24.	Tri-Statin	61
25.	Trituss Er	59
26.	Triumeq	58
27.	Troxerutin	60
28.	Tru-Blu C-Hex 110	56
29.	Trulicity	61

No.	Name	POCA Score (%)
30.	(b) (4) ***	62
31.	Trusopt	62
32.	Truxcillin	64
33.	Truxcillin-Vk	60
34.	Tums Ultra	56
35.	Tusnel C	58
36.	Tusnel Hc	58
37.	Tusnel Syrup	55
38.	Tussi Press	56
39.	Tussirex	58
40.	Verrustat	55

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:** Truseltiq **Established name:** infigratinib **Dosage form:** Capsules **Strength(s):** 25 mg and 100 mg **Usual Dose:** 50 mg, 75 mg, 100 mg, or 125 mg orally once daily on days 1-21 of each 28-day cycle	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.	Pristiq	68	This name pair has sufficient orthographic and phonetic differences.
2.	Protostat	56	This name pair has sufficient orthographic and phonetic differences.
3.	Rauserpin	57	This name pair has sufficient orthographic and phonetic differences.
4.	Rexulti	62	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
6.	Telotristat	56	This name pair has sufficient orthographic and phonetic differences.
7.	Torisel	60	This name pair has sufficient orthographic and phonetic differences.
8.	Trav-L-Tabs	58	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4) ***	61	This name pair has sufficient orthographic and phonetic differences.
10.	Trintellix	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Truseltiq **Established name:** infigratinib **Dosage form:** Capsules **Strength(s):** 25 mg and 100 mg **Usual Dose:** 50 mg, 75 mg, 100 mg, or 125 mg orally once daily on days 1-21 of each 28-day cycle	**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**
11.	Triostat	58	This name pair has sufficient orthographic and phonetic differences.
12.	Trisenox	59	This name pair has sufficient orthographic and phonetic differences.
13.	Trodelvy	56	This name pair has sufficient orthographic and phonetic differences.
14.	Truphylline	58	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4) ***	65	(b) (4)

No.	**Proposed name:** Truseltiq **Established name:** infigratinib **Dosage form:** Capsules **Strength(s):** 25 mg and 100 mg **Usual Dose:** 50 mg, 75 mg, 100 mg, or 125 mg orally once daily on days 1-21 of each 28-day cycle	**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** (b) (4)

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

No.	Name	POCA Score (%)
1.	Liquituss Elixir	48
2.	Proferdex	49
3.	Trysul	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
1.	Citrus Pectin	56	This is an ingredient in a veterinary product.
2.	Ferus Pic-150	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
3.	Frusemek	58	International product marketed in the UK.
4.	Frusetic	76	International product formerly marketed in the UK.
5.	Lutrelin	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
6.	Prepulsid	63	International product marketed in various countries.
7.	Propulsid	62	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
8.	Terrasil	55	International product formerly marketed in Thailand.
9.	Tolrestat	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Torbugesic	56	Veterinary product.
11.	Totaretic	60	International product marketed in the UK.
12.	Tranilast	58	This is a bulk powder used for compounding.
13.	(b) (4) ***	58	Proposed proprietary name for ANDA 210612 withdrawn by the Applicant on November 15, 2018. ANDA 210612 was approved under the established name.
14.	Treosulfan	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Triacetin	60	This product is not a drug. It is a food additive.
16.	Tricetin	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Triclosept	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Trideceth-10	55	Product is not a drug. It is a chemical used in cosmetics.
19.	Trideceth-12	55	Product is not a drug. It is a chemical used in cosmetics.

No.	Name	POCA Score (%)	Failure preventions
20.	Trideceth-3	55	Product is not a drug. It is a chemical used in cosmetics.
21.	Trideceth-5	55	Product is not a drug. It is a chemical used in cosmetics.
22.	Trideceth-6	55	Product is not a drug. It is a chemical used in cosmetics.
23.	Trideceth-8	55	Product is not a drug. It is a chemical used in cosmetics.
24.	Trideceth-9	55	Product is not a drug. It is a chemical used in cosmetics.
25.	Triferic (b) (4)***	56	Proposed proprietary name for IND 051290 and NDA 212860 found unacceptable by DMEPA (OSE# 2019-33305611 and 2019-33305369 dated 10/21/2019). NDA 212860 approved under the proprietary name Triferic AVNU.
26.	Triflusal	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Trihist Cs	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Trihist-D	55	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
29.	Tripalmitin	56	Product is not a drug. It is a triglyceride derived from the fatty acid palmitic acid.
30.	Triposed	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
31.	Trisilane	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Trisofed	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Trital Sr	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
34.	(b) (4) ***	59	Proposed proprietary name for IND 118313 found unacceptable by DMEPA (OSE# 2018-22563733 dated October 18, 2018). NDA 212122 approved under the proprietary name Breztri Aerosphere.
35.	Tri-Zel	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
36.	(b) (4) ***	64	(b) (4)
37.	(b) (4) ***	62	
38.	(b) (4) ***	56	

No.	Name	POCA Score (%)	Failure preventions
39.	(b) (4)***	65	(b) (4)*** is not a drug name but a proposed modifier for the root name "(b) (4)".
40.	Tussiden C	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
41.	(b) (4)***	56	Proposed proprietary name (b) (4)*** found unacceptable under NDA 209405 (RCM# 2019-36530689 dated March 13, 2020). NDA 209405 approved under the proprietary name Tyblume (RCM# 2020-38936684).

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

No.	Name	POCA Score (%)
1.	Atorvaliq	58
2.	Atrosept	60
3.	Atrosulf-1	56
4.	Atruviq	56
5.	Baseretic	57
6.	Citrucel	58
7.	Citrucel Sf	64
8.	Cresatin	58
9.	Cresylate	59
10.	Dustitek	57
11.	Estrostep 21	56
12.	Lucentis	56
13.	Lutrepulse	58

[h] 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 (%)
14.	Nitrostat	55
15.	Pre Folic	58
16.	Prevalite	56
17.	Pro Pet Liquid	56
18.	Prohist Lq	61
19.	Prolastin	56
20.	Protilase	57
21.	Prulet	55
22.	Quercetin	55
23.	Resylto	56
24.	Rotersept	58
25.	Serostim Lq	59
26.	Steri-Stat	58
27.	Steritalc	56
28.	Striverdi	57
29.	Ultralytic	57
30.	Ultralytic 2	57
31.	Vaseretic	56
32.	Vaseretic 10-25	56
33.	Vaseretic 5-12.5	56
34.	Vitrasert	58

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JANINE A STEWART
12/23/2020 02:58:50 PM

ASHLEIGH V LOWERY
12/23/2020 03:18:35 PM