

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

213973Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	April 14, 2020
Application Type and Number:	NDA 213973
Product Name and Strength:	Qinlock (ripretinib) tablets, 50 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Deciphera Pharmaceuticals LLC (Deciphera)
Panorama #:	2020-38981208
DMEPA Primary Reviewer:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Qinlock, which was found unacceptable under NDA 213973 on March 6, 2020.^a The proposed proprietary name, Qinlock, was found to be vulnerable to medication errors due to confusion with another product, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Qinlock, was dependent upon which underlying application was approved first.

We note that the action date for NDA 213973 is May 18, 2020, whereas the underlying application for (b) (4)*** remains in IND status. Therefore, if the proposed proprietary name, Qinlock, is granted approval under NDA 213973 on or before May 18, 2020, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***. Thus, Deciphera resubmitted the proposed proprietary name, Qinlock, for review.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

Upon re-assessment of the proposed proprietary name and proposed product characteristic information, we note that the indication was revised slightly (b) (4) to “indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with imatinib, sunitinib, and regorafenib.” We evaluated the previously identified names of concern considering the revised indication, as well as any lessons learned from recent post-marketing experience which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The April 2, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4)***, and determined that if NDA 213973 for Qinlock is approved on or before the May 18, 2020, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)*** given the underlying application for (b) (4)*** remains in IND status.

Based upon our safety assessment of the proposed proprietary name, Qinlock, the application action date for NDA 213973, and the status of the underlying application for (b) (4)***, we find Qinlock conditionally acceptable.

2.2 COMMUNICATION OF DMEPA’S ANALYSIS

DMEPA communicated our findings to the Division of Oncology 3 (DO3) via e-mail on April 7, 2020.

^a Thomas, S. Proprietary Name Review for Qinlock (IND 125279 and NDA 213973). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MARCH 6. Panorama No. 2019-35523453 and 2019-36473885.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Qinlock, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO DECIPHERA PHARMACEUTICALS LLC

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

If any of the proposed product characteristics as stated in your submission, received on April 3, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

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.

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/

SARAH E THOMAS
04/14/2020 02:28:05 PM

CHI-MING TU
04/14/2020 02:41:36 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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Date of This Review:	March 6, 2020
Application Type and Number:	IND 125279 and NDA 213973
Product Name and Strength:	Qinlock (ripretinib) tablets, 50 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Deciphera Pharmaceuticals LLC (Deciphera)
Panorama #:	2019-35523453 and 2019-36473885
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director:	Danielle Harris, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Qinlock, 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. Deciphera 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 November 1, 2019 under the IND and December 13, 2019 under the NDA, as well as in the February 10, 2020 amendments to the IND and NDA proprietary name submissions.

- Intended Pronunciation: kin' lok
- Active Ingredient: ripretinib
- Indication of Use: treatment of patients with advanced gastrointestinal stromal tumors (GIST) who have received (b) (4).
- Route of Administration: oral
- Dosage Form: tablets
- Strength: 50 mg
- Dose and Frequency: 150 mg (three 50 mg tablets) once daily with or without food. Dose modifications for adverse reactions are: 100 mg once (b) (4) daily.
- How Supplied: 90-count bottles
- Storage: Store in the original container at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature].

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

Deciphera did not provide a derivation or intended meaning for the proposed proprietary name, Qinlock, 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, November 15, 2019 and February 3, 2020 e-mails, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Qinlock at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA's prescription studies for Qinlock.

One of the CPOE study participants interpreted the proposed proprietary name as (b) (4) *** which is a direct hit to a proprietary name currently under review. We investigated this result and discussed the response with the study participant; the response was determined to be an erroneous response, and thus, was not evaluated further.

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^b identified 25 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 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. 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 $\geq 70\%$	1

^a USAN stem search conducted on November 27, 2019.

^b POCA search conducted on November 27, 2019 in version 4.3.

Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	21
Low similarity name pair: combined match percentage score $\leq 54\%$	3

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

We determined 24 of the 25 names will not pose a risk for confusion with Qinlock as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4)***. The rationale for the risk of confusion is described below.

Qinlock vs. (b) (4)***

The proposed proprietary name, Qinlock, may be confused with another pending proposed proprietary name that is also under review, (b) (4)

(b) (4)

(b) (4)

^c POCA search conducted on November 27, 2019 in version 4.3.

^d Institute for Safe Medication Practices. Safety briefs: Vitamin D-angerous? ISMP Med Saf Alert Community/Ambulatory Care. 2012; 11(11): 1-4.

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.

Therefore, based on the totality of the information above, we find the proposed proprietary name, Qinlock, vulnerable to medication errors due to name confusion with (b) (4)***.

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 February 27, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 3 (DO3) on March 2, 2020, they stated no additional concerns with the proposed proprietary name, Qinlock.

3 CONCLUSION

The proposed proprietary name, Qinlock, is not acceptable from a safety perspective. The proposed proprietary name, Qinlock, is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the name will be communicated to Deciphera via letter (See Section 3.1).

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

3.1 COMMENTS TO DECIPHERA PHARMACEUTICALS LLC

^e Institute for Safe Medication Practices. Safety Briefs. ISMP Med Saf Alert Acute Care. 1999;4(18):2.

^f 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.

We have completed our review of the proposed proprietary name, Qinlock, and have concluded that this name is unacceptable. The proposed proprietary name, Qinlock, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Qinlock, 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 Qinlock, you will be requested to submit another name.

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.^g

^g 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (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^h. 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.

^h 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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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

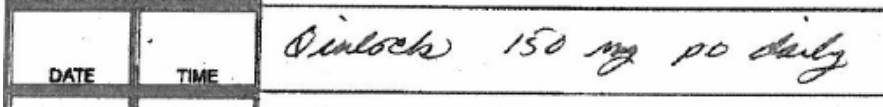
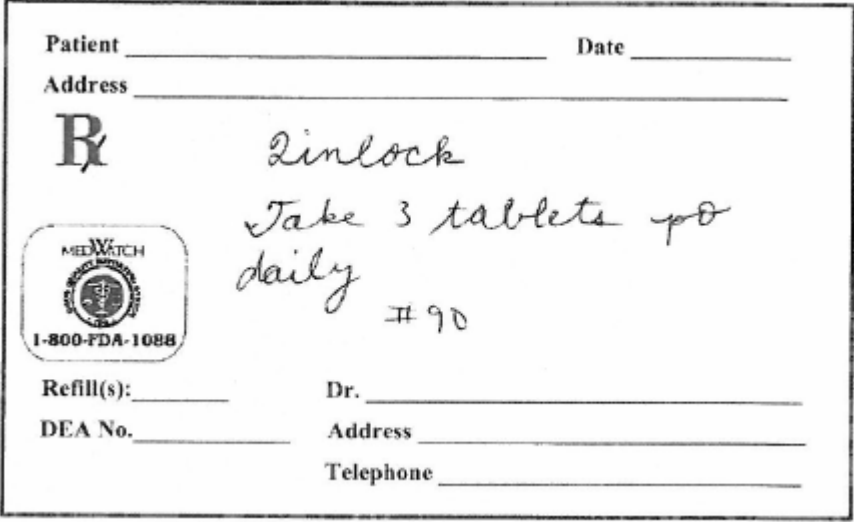
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Qinlock Study (Conducted on November 15, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Qinlock Take three tablets by mouth daily dispense ninety
CPOE Study Sample (Font: sans-serif, 12 point, bold)	
Qinlock	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Qinlock

As of Date 1/17/2020

212 People Received Study

93 People Responded

Study Name: Qinlock

Total	20	37	20	16	93
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
DINLOCK	1	0	0	0	1
KENLOCK	0	0	5	0	5
KENLOK	0	0	1	0	1
KIMLOC	0	0	1	0	1
KINHARTO	0	1	0	0	1
KINLOC	0	0	3	0	3
KINLOCH	0	0	1	0	1
KINLOCK	0	0	8	0	8
LINLOCK	2	0	0	0	2
QINLOCH	0	0	0	2	2
QINLOCK	6	36	0	13	55
QINLOCKS	0	0	0	1	1
QUINWAC	0	0	1	0	1
ZINLOCK	11	0	0	0	11

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

No.	Proposed name: Qinlock Established name: ripretinib Dosage form: tablets Strength(s): 50 mg Usual Dose: 150 mg orally once daily. Dose modification for adverse reactions to 100 mg ^{(b) (4)} once daily.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Qinlock	100	Proposed proprietary name is the subject of this review.

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

No.	Name	POCA Score (%)
	N/A	

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Qinlock Established name: ripretinib Dosage form: tablets Strength(s): 50 mg Usual Dose: 150 mg orally once daily. Dose modification for adverse reactions to 100 mg ^{(b) (4)} once daily.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Hep-Lock	61	This name pair has sufficient orthographic and phonetic differences. In addition, Qinlock and Hep-Lock are available in multiple non-overlapping strengths (50 mg versus 10 units/mL and 100 units/mL). The products also differ in dosage form (tablets versus solution for injection) and route of administration (oral versus intravenous); thus, these product characteristic differences provide additional differentiation if they are included on a prescription.

No.	Proposed name: Qinlock Established name: ripretinib Dosage form: tablets Strength(s): 50 mg Usual Dose: 150 mg orally once daily. Dose modification for adverse reactions to 100 mg (b) (4) once daily.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	Ivy Block	60	This name pair has sufficient orthographic and phonetic differences.
4.	Kenalog	62	This name pair has sufficient orthographic and phonetic differences. In addition, Qinlock and Kenalog are available in multiple non-overlapping strengths (50 mg versus 0.147 mg/gm, 0.025%, 0.1%, 0.5%), as well as differ in dosage form (tablets versus spray, cream, ointment, lotion). Additionally, the products differ in frequency of administration (once daily versus three to four applications daily) and route of administration (oral versus topical); thus, these product characteristic differences provide additional differentiation if they are included on a prescription.
5.	Kenalog-10	62	This name pair has sufficient orthographic and phonetic differences. Although both Qinlock and Kenalog-10 are single strength products where the strength may be omitted on a prescription, the name pair differs in route of administration (orally versus intra-articular or intralesional). Additionally, the products differ in dosage form (tablets versus injectable suspension, USP); thus, this product characteristic difference provides additional differentiation if included on a prescription.
6.	Kenalog 40	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Qinlock Established name: ripretinib Dosage form: tablets Strength(s): 50 mg Usual Dose: 150 mg orally once daily. Dose modification for adverse reactions to 100 mg (b) (4) once daily.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			In addition, Qinlock and Kenalog 40 are available in multiple non-overlapping strengths (50 mg versus 40 mg/mL, 200 mg/5 mL, and 400 mg/10 mL), as well as differ in route of administration (oral versus intramuscular or intra-articular). Additionally, the products differ in dosage form (tablets versus injectable suspension, USP); thus, this product characteristic difference provides additional differentiation if included on a prescription.
7.	Kenalog-40	62	This name pair has sufficient orthographic and phonetic differences. In addition, Qinlock and Kenalog-40 are available in multiple non-overlapping strengths (50 mg versus 40 mg/mL, 200 mg/5 mL, and 400 mg/10 mL), as well as differ in route of administration (oral versus intramuscular or intra-articular). Additionally, the products differ in dosage form (tablets versus injectable suspension, USP); thus, this product characteristic difference provides additional differentiation if included on a prescription.
8.	Kenalog-80	62	This name pair has sufficient orthographic and phonetic differences. In addition, Qinlock and Kenalog-80 are available in multiple non-overlapping strengths (50 mg versus 400 mg/5 mL, 80 mg/mL), as well as differ in route of administration (oral

No.	Proposed name: Qinlock Established name: ripretinib Dosage form: tablets Strength(s): 50 mg Usual Dose: 150 mg orally once daily. Dose modification for adverse reactions to 100 mg (b) (4) once daily.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			versus intramuscular or intra-articular). Additionally, the products differ in dosage form (tablets versus injectable suspension, USP); thus, this product characteristic difference provides additional differentiation if included on a prescription.
9.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
10.	Lincocin	42	This name pair has sufficient orthographic and phonetic differences.
11.	Mino-Lok***	69	This name pair has sufficient orthographic and phonetic differences.
12.	Penlac	64	This name pair has sufficient orthographic and phonetic differences.
13.	Tymlos	54	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
	N/A	

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
14.	Chemdec	44	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
15.	Kinlytic	62	Brand discontinued with no generic equivalents available per Micromedex Redbook database.

No.	Name	POCA Score (%)	Failure preventions
16.	P Bloc	58	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 confusionⁱ.

No.	Name	POCA Score (%)
17.	Cinalog	65
18.	Clinac	60
19.	Clinalog	62
20.	Kinevac	57
21.	Pindac	56
22.	Rinvoq	56
23.	Siklos	56
24.	Tumil-K	55

ⁱ 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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