CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217581Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

Date of This Review:	February 17, 2023
Application Type and Number:	NDA 217581
Product Name and Strength:	Xalkori (crizotinib) Oral Granules, 20 mg, 50 mg, and 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer Inc. (Pfizer)
PNR ID #:	2022-1044724861
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

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

1.1 BACKGROUND

Pfizer currently markets the active ingredient, crizotinib, under the proprietary name Xalkori (NDA 202570), which is available as 200 mg and 250 mg hard gelatin capsules (to be swallowed whole). Pfizer is now seeking a product line extension for a formulation of crizotinib proposed as oral granules contained inside capsules to be supplied in 20 mg, 50 mg, and 150 mg strengths. The proposed product is designed such that the capsules are to be opened (not swallowed whole, crushed, or chewed) and the oral granule contents sprinkled directly into the mouth or administered via a consumer-supplied dosing aid (spoon, cup), followed by water. This proposed oral granule formulation is intended for pediatric patients unable to swallow whole capsules and to extend the dose range below that attainable with the currently available Xalkori capsules.

On November 29, 2022, Pfizer submitted for our review the proprietary name, Xalkori, under NDA 217581 for the newly proposed oral granules formulation.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 29, 2022.

- Intended Pronunciation: zal-KOR-ee
- Active Ingredient: crizotinib
- Indication of Use:
    - treatment of pediatric patients 1 year of age and older with relapsed or refractory, systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive.
    - treatment of pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is anaplastic lymphoma kinase (ALK)-positive.
- Route of Administration: Orally by one of two options:
    - Opening capsule(s) containing the oral granules and emptying the contents directly into the patient's mouth.
      OR
    - Opening capsule(s) containing the oral granules and emptying the contents into a consumer-supplied oral dosing aid (e.g., spoon, medicine cup). The oral granules are then administered to the patient's mouth via the dosing aid, followed by water.
- Dosage Form: Oral Granules
- Strength: 20 mg, 50 mg, and 150 mg

- Dose and Frequency: 280 mg/m^2 orally twice daily until disease progression or unacceptable toxicity.

Body Surface Area** (BSA)	Dose (Twice Daily)	Total Daily Dose
0.38 to 0.46 m^2	120 mg (1 x 20 mg + 2 x 50 mg)	240 mg
0.47 to 0.51 m^2	140 mg (2 x 20 mg + 2 x 50 mg)	280 mg
0.52 to 0.61 m^2	150 mg (1 x 150 mg)	300 mg
0.62 to 0.80 m^2	200 mg (1 x 50 mg + 1 x 150 mg)	400 mg
0.81 to 0.97 m^2	250 mg (2 x 50 mg + 1 x 150 mg)	500 mg
0.98 to 1.16 m^2	300 mg (2 x 150 mg)	600 mg
1.17 to 1.33 m^2	350 mg (1 x 50 mg + 2 x 150 mg)	700 mg

*Refers to the 150 mg, 50 mg, and 20 mg XALKORI oral granules.
**The recommended dosage for patients with a BSA less than 0.38 m^2 has not been established.

- How Supplied: Bottles of 60 capsules
- Storage: Store at room temperature 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

2 METHODS AND DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Xalkori would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Xalkori. The Division of Oncology 2 (DO2) did not comment on the findings of OPDP's assessment for Xalkori.

2.2 SAFETY ASSESSMENT

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

Pfizer did not provide a derivation or intended meaning for the proposed proprietary name, Xalkori, in their submission. This proprietary name is comprised of a single word. We note that the proposed proprietary name contains the following medical abbreviation:

[a] USAN stem search conducted on January 5, 2023.

- OR = Operating Room

Although we typically discourage the inclusion of medical abbreviations in the proprietary names, "or" is a common letter string in proprietary names (e.g. Anoro Ellipta, Dysport, Forteo, Symbicort) and we are unaware of any post-market reports of name confusion medication error associated with this specific abbreviation. We determined that the location of this abbreviation in the infix of the name is unlikely to be separated from the surrounding letters or be misunderstood within the context of a prescription that could lead to confusion. Therefore, in this case we do not object to the letter string "or" in the proposed proprietary name.

Beyond these noted abbreviations, we note that Xalkori does not contain any additional 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

On December 8, 2022, the Division of Oncology 2 (DO2) did not forward any comments or concerns relating to Xalkori at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety practitioners participated in DMEPA's prescription studies for Xalkori. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2. 3 *Multiple Dosage Forms Under a Single Proprietary Name*

The applicant has proposed to market two dosage forms, capsules and oral granules, under the same proprietary name to cover both pediatric and adult patients for treatment of the approved indications. In their November 29, 2022 submission, Pfizer submitted a clinical overview which included comparative bioavailability and bioequivalence study data[b] comparing the proposed oral granules to the approved capsule formulation. Pfizer concluded the oral granules were bioequivalent to the approved Xalkori 200 mg and 250 mg capsules. Further, Pfizer determined the proposed crizotinib oral granules are safe for patients in the event a patient accidently swallows the capsules whole. The relative bioavailability of oral granules administered as whole capsules compared to oral granules emptied into the mouth was 105% and no new safety issues were identified when the oral granules were administered as whole capsules. At the time of this review, these study results are pending confirmation by the Office of Pharmaceutical Quality (OPQ).

Table 1 below compares the currently marketed capsule formulation (to be swallowed whole) and the proposed pediatric oral granules formulation (oral granule inside capsule where capsule is to be opened and contents poured into mouth).

[b]Clinical Overview for Xalkori (crizotinib) NDA 217581. April 28, 2022. \\CDSESUB1\EVSPROD\nda217581\0001\m2\25-clin-over\clinical-overview.pdf

Table 1. Product Characteristics of Xalkori (hard gelatin capsules) and Xalkori (capsules containing oral granules)		
	Xalkori[c]	**Xalkori (proposed)**
Application Number	NDA 202570	NDA 217581
Active Ingredient	crizotinib	crizotinib
Indication	• patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test. • pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. o Limitations of Use: The safety and efficacy of XALKORI have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL. adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.	
Route of Administration	Oral (swallowed whole)	Oral (opened and contents poured into mouth)
Strength	200 mg and 250 mg	20 mg, 50 mg, and 150 mg
Dose and Frequency	Metastatic NSCLC: The recommended dosage is 250 mg orally twice daily. Systemic ALCL: The recommended dosage is 280 mg/m^2 orally twice daily based on body surface area. Unresectable IMT: • Adult: The recommended dosage is 250 mg orally twice daily.	

[c] Xalkori. DailyMed. National Library of Medicine; January 2023. Available from https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=2a51b0de-47d6-455e-a94c-d2c737b04ff7&type=pdf

	• Pediatric: The recommended dosage is 280 mg/m^2 orally twice daily based on body surface area.	
Dosage Form	Capsules (hard gelatin)	Oral granules (inside a capsule)
How Supplied	Bottles of 60 capsules	
Storage:	Store at room temperature 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].	

We note that the proposed dosage forms share the same active ingredient, indication, route of administration, and frequency of administration. It is a common and accepted practice to have multiple dosage forms of an active ingredient managed under one proprietary name. Additionally, our routine postmarketing surveillance has not identified any signals attributed to name confusion involving Xalkori. We further acknowledge that, when marketing under the same proprietary name, the differences between the two dosage forms such as the different strengths and the different the method of oral administration (open capsule to sprinkle the oral granules vs. swallow capsule whole) can be communicated and differentiated by labels and labeling.

Therefore, given the aforementioned considerations, we do not object to the Applicant's proposal to market the proposed product with the proprietary name, Xalkori.

2.2.5 Communication of DMEPA's Determination

On February 17, 2023, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

3 CONCLUSION

The proposed proprietary name, Xalkori, is conditionally acceptable.

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

3.1 COMMENTS TO PFIZER INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 29, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

[d] 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, Cerner RxNorm, 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., 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

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

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

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

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *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. Xalkori Study (Conducted on December 29, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: Xalkori Administer contents of 150mg capsule po BID Outpatient Prescription: Patient _____ Date 12-29-22 Address _____ ℞ Xalkori 150mg Open capsule and pour contents into mouth BID. #60 MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. OSE DEA No._____ Address _____ Telephone _____	Xalkori 150mg Open capsule and pour contents into mouth twice daily Dispense 60
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Xalkori	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Xalkori
As of Date 2/13/2023

259 People Received
Study
90 People Responded

Study Name: Xalkori

Total	22	25	19	24	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
XALCORI	0	0	1	2	3
XALKHORI	0	0	0	1	1
XALKORI	22	25	1	19	67
ZALCOREY	0	0	1	0	1
ZALCORI	0	0	5	0	5
ZALCORY	0	0	2	0	2
ZALKORI	0	0	2	2	4
ZALKORY	0	0	3	0	3
ZALPOREY	0	0	1	0	1
ZALPORY	0	0	1	0	1
ZALPRI	0	0	1	0	1
ZELCORY	0	0	1	0	1

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