CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215039Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 24, 2021
Application Type and Number:	NDA 215039
Product Name and Strength:	Vijoice (alpelisib) Tablets, 50 mg, 125 mg, and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novartis Pharmaceuticals Corp. (Novartis)
PNR ID #:	2021-1044724056
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Novartis previously submitted the proposed proprietary name, Vijoice on November 27, 2019. We found the name, Vijoice, conditionally acceptable under IND 143387 on May 20, 2020..[a]

Thus, Novartis submitted the name, Vijoice, for review under NDA 215039 on July 12, 2021. We note that all product characteristics for the proposed tablet dosage form remain the same since our last review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 12, 2021.[b]

- Intended Pronunciation: Vi joys'
- Active Ingredient: alpelisib
- Indication of Use: For the treatment of adult and pediatric patients aged 2 years and older with PIK3CA-related overgrowth spectrum (PROS)
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: Tablets: 50 mg, 125 mg, and 200 mg.
- Dose and Frequency:
    - Patients 2-17 years: 50 mg once daily (maximum daily dose)
    - Patients ≥18 years: 250 mg once daily (maximum daily dose)
        - First-dose reduction: (b) (4) mg once daily
        - Second-dose reduction (b) (4) mg once daily
        - (b) (4)

[a] Stewart, J. Proprietary Name Review for Vijoice (IND 143387). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAY 20. PNR ID No. 2019-36120321.

[b] We note that the Request for Proprietary Name Review (b) (4) (b) (4)

- How Supplied: Carton containing blister pack(s) of tablets.
- Storage: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].
- Reference Listed Drug/Reference Product: Piqray (alpelisib) Tablets NDA 212526

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vijoice would not misbrand the proposed product. The Division of Oncology 2 (DO2) did not object to the proposed name, but expressed that the proposed name Vijoice evokes the word "rejoice". This comment was shared with OPDP who re-evaluated the proposed name and determined that the connection between the proposed proprietary name and "rejoice" was not sufficiently definitive to support an objection. Thus, OPDP maintained their non-objection to the proposed proprietary name from a promotional perspective. After further correspondence, DO2, deferred to OPDP's assessment and did not require further discussion. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with OPDP's misbranding assessment for Vijoice.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Novartis did not provide a derivation or intended meaning for the proposed proprietary name, Vijoice, 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 August 2, 2021 email, the Division of Oncology 2 (DO2) forwarded a concern related to the proposed proprietary name, Vijoice , at the initial phase of the review (see Section 2.1).

[c] USAN stem search conducted on July 14, 2021.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 43 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. We had identified and evaluated 42 of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 1 name not previously analyzed. The name is 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 ≥70%	-
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	1
Low similarity name pair: combined match percentage score ≤54%	-

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

Our analysis of the 1 name contained in Table 1 determined the name will not pose a risk for confusion with Vijoice as described in Appendix H.

2.2.8 Discussion of Dual Proprietary Names

Novartis currently markets alpelisib tablets under the proprietary name Piqray which is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA approved test

[d] POCA search conducted on July 14, 2021 in version 4.4.

following progression on or after an endocrine-based regimen under NDA 212526. Novartis now proposes the dual proprietary name, Vijoice, for the treatment of PIK3CA-related overgrowth spectrum (PROS) in adult and pediatric patients aged 2 years and older.

Novartis is proposing a dual proprietary name for alpelisib tablets for the following reasons:

- To minimize the dosing confusion by having distinct Prescribing Information (PI) for the different indications.
- To minimize the stigma associated with the use of the proposed product for PROS with the Piqray name for breast cancer.
- To help minimize the risk of medication errors, such as overdose, from having six blister pack configurations under a single proprietary name.
- To help post-market pharmacovigilance monitoring by using different proprietary names.

Table 2 presents relevant information for Vijoice and Piqray.

Table 2. Relevant Product Information for Vijoice and Piqray

Product Name	**Vijoice (proposed proprietary name)**	**Piqray (currently marketed proprietary name)**
Initial Approval Date	N/A	May 24, 2019
Intended Pronunciation	Vi joiz	pik' raye
Active Ingredient	alpelisib	alpelisib
Indication	Indicated in adult and pediatric patients aged 2 year and older for the treatment of PIK3CA-related overgrowth spectrum (PROS).	Indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated advanced or metastatic breast cancer as detected by an FDA approved test following progression on or after an endocrine-based regimen.
Route of Administration	Oral	Oral
Dosage Form	Tablets	Tablets
Strength	Tablets: 50 mg, 125 mg, 200 mg	Tablets: 50 mg, 150 mg, 200 mg
Dose and Frequency	Maximum daily dose in adult patients: 250 mg once daily. • First dose reduction: (b) (4) mg once daily • Second dose reduction: (b) (4) mg once daily	Maximum daily dose: 300 mg (two 150 mg tablets) once daily. Dose modifications for adverse reactions:

Table 2. Relevant Product Information for Vijoice and Piqray		
Product Name	**Vijoice (proposed proprietary name)**	**Piqray (currently marketed proprietary name)**
	• (b) (4) Maximum daily dose pediatric patients: 50 mg once daily	• First dose reduction: 250 mg (one 200 mg tablet and one 50 mg tablet) once daily. • Second-dose reduction: 200 mg (one 200 mg tablet) once daily. • If further dose reduction below 200 mg once daily is required discontinue PIQRAY.
How Supplied	**250 mg daily dose:** Each carton contains 2 blister packs (56 tablets total). Each blister pack contains 28 tablets (14 tablets, 200 mg alpelisib per tablet and 14 tablets, 50 mg alpelisib per tablet) **125 mg daily dose:** Each carton contains 1 blister pack (28 tablets total). Each blister pack contains 28 tablets (28 tablets, 125 mg alpelisib per tablet) **50 mg daily dose:** Each carton contains 1 blister pack (28 tablets total). Each blister pack contains 28 tablets (28 tablets, 50 mg alpelisib per tablet) (b) (4)	**300 mg daily dose:** Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (28 tablets, 150 mg alpelisib per tablet). **250 mg daily dose:** Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (14 tablets, 200 mg alpelisib per tablet and 14 tablets, 50 mg alpelisib per tablet). **200 mg daily dose:** Each carton contains 1 blister pack. Each blister pack contains a 28-day supply of 28 tablets (28 tablets, 200 mg alpelisib per tablet).

We have evaluated the risks associated with this naming strategy and do not object to the use of a dual proprietary name in this case.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Oncology 2 (DO2). At that time we also requested additional information or concerns that could inform our review. On September

23, 2021, the Division of Oncology 2 (DO2) stated no additional concerns with the proposed proprietary name, Vijoice.

3 CONCLUSION

The proposed proprietary name, Vijoice, is acceptable.

If you have any questions or need clarifications, please contact Capt. Latonia Ford, OSE project manager, at 301-796-9401.

3.1 COMMENTS TO NOVARTIS PHARMACEUTICALS CORP.

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

If any of the proposed product characteristics as stated in your submission, received on July 12, 2021, and clarified on September 24, 2021[e], are altered prior to approval of the marketing application, the name must be resubmitted for review.

[e] Response to Proprietary Name Review Information Request. East Hanover NJ, Novartis Pharmaceuticals Corp. 2021 SEP 24. Available at: \\CDSESUB1\evsprod\nda215039\0010\m1\us\cover.pdf

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.

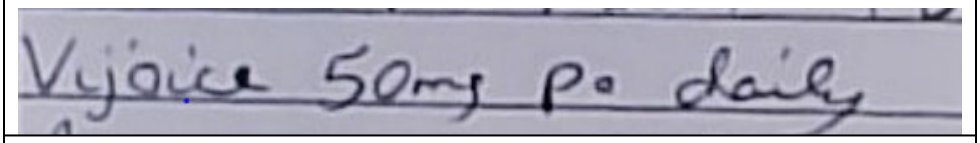
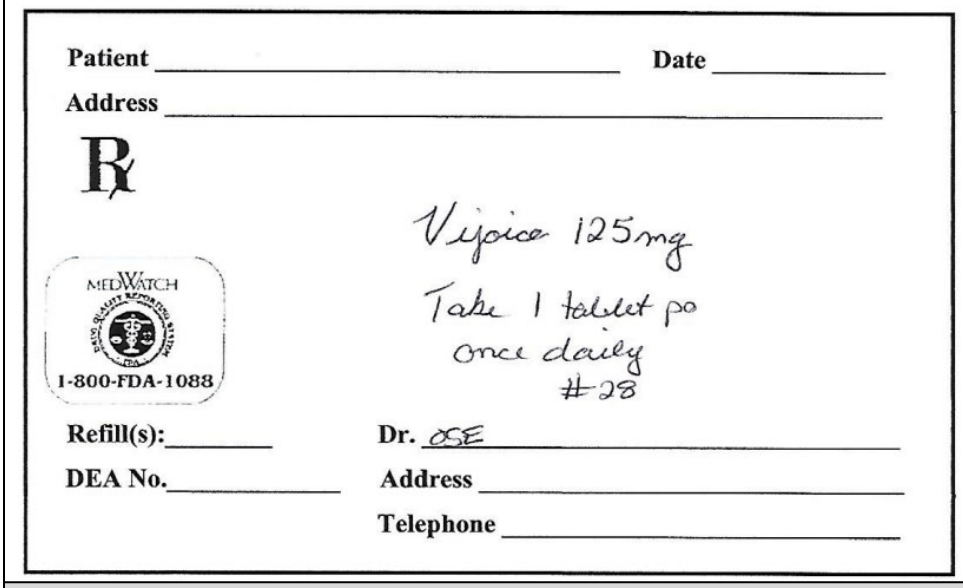
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Vijoice Study (Conducted on July 23, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Vijoice Take 1 tablet by mouth once daily Dispense #28
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vijoice	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vijoice
As of Date 8/2/2021

265 People Received
Study
125 People Responded

Study Name: Vijoice

Total	28	31	37	29	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
BYJOYCE	0	0	1	0	1
VEJOICE	1	0	0	1	2
VIJOICA	1	0	0	0	1
VIJOICE	26	31	5	27	89
VIJOICE 125 MG	0	0	1	0	1
VIJOINCE	0	0	1	0	1
VIJOYCE	0	0	3	0	3
VYJOICE	0	0	11	0	11
VYJOYCE	0	0	14	0	14
VYJOYZ	0	0	1	0	1
VYSICE	0	0	0	1	1

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

No.	**Proposed name:** Vijoice **Established name:** alpelisib **Dosage form:** Tablets **Strength(s):** 50 mg, 125 mg, and 200 mg **Usual Dose:** Adults: 250 mg once daily Pediatrics: 50 mg 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.	Vijoice	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 (%)
	N/A	

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

No.	**Proposed name:** Vijoice **Established name:** alpelisib **Dosage form:** Tablets **Strength(s):** 50 mg, 125 mg, and 200 mg **Usual Dose:** Adults: 250 mg once daily Pediatrics: 50 mg 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**
	N/A		

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤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
	N/A		

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.	Rivive***	56

[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

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