CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208716Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	May 23, 2017
Application Type and Number:	IND 106100 NDA 208716
Product Name and Strength:	Verzenio (Abemaciclib) Tablets, 50 mg, 100 mg, 150 mg, 200 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eli Lilly and Company (Eli Lilly)
Panorama #:	2017-14018751 (IND 106100) 2017-14948718 (NDA 208716)
DMEPA Primary Reviewer:	Grace P. Jones, PharmD, BCPS
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Verzenio, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Sponsor did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Eli Lilly previously submitted the proposed proprietary name (b) (4) for abemaciclib capsules, 50 mg, 75 mg, and 100 mg, on July 17, 2015 under IND 106100. The Division of Medication Error Prevention and Analysis (DMEPA) found the name (b) (4) conditionally acceptable on November 6, 2015 (OSE Review #2015-992902)[a].

Eli Lilly then re-submitted the request for proprietary name review on November 22, 2016 for the proposed proprietary name (b) (4) under IND 106100 because of a change in product characteristics. Eli Lilly considered adding a new tablet dosage form. Subsequently, Eli Lilly finalized their development plans and decided not to pursue the capsule dosage form. Therefore, Eli Lilly submitted an amendment to the request for proprietary name review on February 2, 2017, for the proposed proprietary name (b) (4) for only the tablets, 50 mg, 100 mg, 150 mg, and 200 mg.[b]

Upon re-review of the proposed name, we communicated to Eli Lilly via teleconference on March 9, 2017[c] and March 21, 2017[d] that the proposed name (b) (4) contains the United States Adopted Name (USAN) stem -io- in the infix position. The USAN stem -io- indicates iodine-containing contrast media products, which the proposed product is not an iodine-containing contrast media product, making the proposed name misleading. Both Eli Lilly's external name study and DMEPA did not identify this USAN stem -io- during our previous reviews. On March 22, 2017, the Sponsor withdrew the proposed proprietary name (b) (4) from IND 106100.

On March 29, 2017, Eli Lilly submitted the proposed proprietary name, Verzenio, for review under IND 106100. On May 5, 2017, Eli Lilly submitted the new drug application for abemaciclib tablets, 50 mg, 100 mg, 150 mg, and 200 mg. At the same time on May 5, 2017, Eli Lilly submitted the proposed proprietary name, Verzenio, for review under NDA 208716.

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[a] Jones, GP. Proprietary Name Review for (b) (4) IND 106100. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 NOV 06. RCM No.: 2015-992902.

[b] We did not evaluate whether the capsule and tablet dosage forms can be substituted between the same strengths or between the same doses since the applicant has indicated that they do not intend to pursue the capsule formulation.

[c] Eli Lilly and Company. Sponsor Meeting Minutes. Abemaciclib tablets, IND 106100. Indianapolis (IN): Eli Lilly and Company; 2017 MAR 20.

[d] Eli Lilly and Company. Sponsor Meeting Minutes. Abemaciclib tablets, IND 106100. Indianapolis (IN): Eli Lilly and Company; 2017 APR 03.

In the NDA 208716 name submission, Eli Lilly included the external name study for the previously proposed name [redacted] and indicated [redacted] a repeated external name study for Verzenio would not yield any significantly different results. Moreover, Eli Lilly indicated that they completed additional assessment for Verzenio using the Phonetic Orthographic Computer Analysis (POCA) version 4.0.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 29, 2017 and May 5, 2017 proprietary name submissions.

- Intended Pronunciation: \ver-ZEN-ē-ō\
- Active Ingredient: Abemaciclib
- Indication of Use: Indicated for the treatment of HR+, HER2− metastatic breast cancer in women whose disease has progressed on or after endocrine therapy and who previously received [redacted] chemotherapy [redacted] in the metastatic setting.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 50 mg, 100 mg, 150 mg, 200 mg
- Dose and Frequency:
    - For the initial indication for single-agent use: Initial dose and frequency is 200 mg taken orally twice daily. Dose adjustments will be made based on tolerability in 50 mg decrements. Dosing is continuous without interruption until patient's cancer progresses or the patient has to discontinue for tolerability/toxicity concerns.
    - For subsequent indications in combination with endocrine therapies (Fulvestrant): Initial dose and frequency is 150 mg taken orally twice daily. Dose adjustments will be made based on tolerability in 50 mg decrements.
- How Supplied: Abemaciclib tablets will be packaged in [redacted] blister packaging: 50 mg tablets in 14-count, [redacted] blister packs; 100 mg, 150 mg, and 200 mg tablets in 14-count blister packs
- Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Eli Lilly indicated in their submission that the proposed name, Verzenio, has no specific derivation, is not intended to evoke any particular or specific meaning, and they consider the proposed name to be an "empty vessel." 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, April 7, 2017 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-nine practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 95 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the Sponsor's POCA assessment. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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[e] USAN stem search conducted on April 5, 2017.

[f] POCA search conducted on March 28, 2017 in version 4.0.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	94
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 96 names contained in Table 1 determined 96 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on May 8, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on May 17, 2017, they stated no additional concerns with the proposed proprietary name, Verzenio.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 29, 2017 and May 5, 2017 submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

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

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

***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)).

[g] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

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[h]. We evaluate all moderately similar names retrieved from POCA to

[h] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary

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.

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

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

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

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

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

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

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

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

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

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

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

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

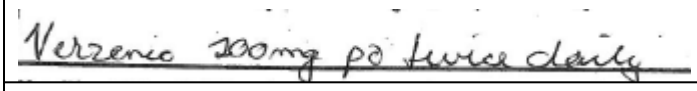
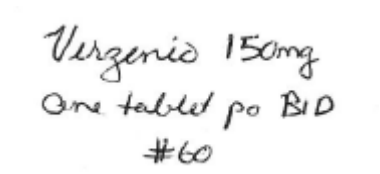
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Verzenio Study (Conducted on April 10, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Verzenio 150 mg take 1 tablet by mouth twice daily Dispense #60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study

79 People Responded

Study Name: Verzenio

Total	**23**	**33**	**23**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
NERZENIO	0	0	1	1
VASINANIO	0	1	0	1
VERGENIO	1	0	0	1
VERIZENIC	0	0	1	1
VERSANIO	0	1	0	1
VERSENIO	0	1	1	2
VERZENCO	0	0	1	1
VERZENEO	0	2	0	2
VERZENIC	2	0	4	6
VERZENIO	14	22	15	51
VERZENNIO	0	1	0	1
VERZIENO	0	1	0	1
VERZINIO	0	1	0	1
VESZENIO	0	1	0	1
VIREZENIO	1	0	0	1
VIRZENIO	5	2	0	7

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

No.	**Proposed name:** Verzenio **Established name:** Abemaciclib **Dosage form:** Tablets **Strength(s):** 50 mg, 100 mg, 150 mg, 200 mg **Usual Dose:** For initial indication single-agent use: 200 mg twice daily, dose adjustments in 50 mg decrements. For subsequent indications in combination therapies: 150 mg twice daily, dose adjustments in 50 mg decrements.	**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.	Verzenio***	100	Name is the subject of this review.
2.	(b) (4)***	90	Previously submitted proposed proprietary name for this IND 106100 that was withdrawn.

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

No.	Name	POCA Score (%)
1.	Dermazene	55
2.	Vaprino	58
3.	Varithena	59
4.	Varizig	56
5.	(b) (4)***	66
6.	(b) (4)***	57
7.	verelan	62
8.	versed	65
9.	Virazole	57
10.	Visine-A	56
11.	Vonvendi	60

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:** Verzenio **Established name:** Abemaciclib **Dosage form:** Tablets **Strength(s):** 50 mg, 100 mg, 150 mg, 200 mg **Usual Dose:** For initial indication single-agent use: 200 mg twice daily, dose adjustments in 50 mg decrements. For subsequent indications in combination therapies: 150 mg twice daily, dose adjustments in 50 mg decrements.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Dyrenium	56	This name pair has sufficient orthographic and phonetic differences.
2.	Everone	55	This name pair has sufficient orthographic and phonetic differences.
3.	Sernivo	67	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Verzenio contains an additional syllable.
4.	Serzone	64	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Verzenio contains two more syllables.
5.	Valergen	58	This name pair has sufficient orthographic and phonetic differences.
6.	Vardenafil	58	This name pair has sufficient orthographic and phonetic differences.
7.	verazinc	68	The infix letter ‘a’ in Verazinc elongates the infix and gives it a different shape as compared with the prefix of Verzenio. The second and third syllables of this name pair sound different and Verzenio contains an additional syllable. Strength: 220 mg versus 50 mg 100 mg, 150 mg, 200 mg.
8.	verdeso	68	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different and Verzenio contains an additional syllable.

No.	**Proposed name:** Verzenio **Established name:** Abemaciclib **Dosage form:** Tablets **Strength(s):** 50 mg, 100 mg, 150 mg, 200 mg **Usual Dose:** For initial indication single-agent use: 200 mg twice daily, dose adjustments in 50 mg decrements. For subsequent indications in combination therapies: 150 mg twice daily, dose adjustments in 50 mg decrements.	**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**
9.	veregen	68	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different and Verzenio contains an additional syllable.
10.	versacloz	56	This name pair has sufficient orthographic and phonetic differences.
11.	Vesanoid	56	This name pair has sufficient orthographic and phonetic differences.
12.	Viberzi	58	This name pair has sufficient orthographic and phonetic differences.
13.	Virilon	58	This name pair has sufficient orthographic and phonetic differences.
14.	Virilon Im	56	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
16.	zenzedi	62	The prefix and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different and Verzenio contains an additional syllable.

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

No.	Name	POCA Score (%)
1.	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
1.	Carzenide	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Cerenia	66	Veterinary product.
3.	Convenia	56	Veterinary product.
4.	Eprozinol	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Geraniol	61	Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available.
6.	Iver-On	58	Veterinary product.
7.	Nerisone	56	International product marketed in France, Hong Kong, South Africa, New Zealand, UK, and Canada.
8.	Orbenin	57	Veterinary product.
9.	Sarenin	55	Name identified in Drugs At FDA. Product is discontinued and withdrawn FR effective 09/29/1995 (under NDA 018009). Unable to find product characteristics in other commonly used drug databases.
10.	(b) (4) ***	58	Name identified in Names Entered by Safety Evaluator database. This name corresponds to BLA 125141; however, BLA 125141 was approved with the proprietary name Myozyme on 04/28/2006.
11.	(b) (4) ***	59	Proposed proprietary name for ANDA 091209 found unacceptable by DMEPA (OSE# 2011-1224 and 2011-1225). Applicant did not submit a new name and ANDA 091209 was approved on 07/22/2010.
12.	veriloid	58	Name identified in Drugs At FDA. Product is discontinued and withdrawn FR effective 06/17/1986 (under NDA 007336). Unable to find product characteristics in other commonly used drug databases.
13.	verluma	56	Name identified in Drugs At FDA database. Unable to find product characteristics in commonly used drug databases.
14.	vermidol	64	Name identified in Drugs At FDA. Product is discontinued and withdrawn FR effective 05/10/1994 (under ANDA 080992). Unable to find product characteristics in other commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
15.	verrugon	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	versapen	61	Name identified in Drugs At FDA. Product is discontinued and withdrawn FR effective 11/5/1992 under NDA 050060 and on 12/17/90 under ANDA 061398 . Unable to find product characteristics in other commonly used drug databases.
17.	vertavis	57	Name identified in Drugs At FDA. Product is discontinued and withdrawn FR effective 11/5/1992 under NDA 005691. Unable to find product characteristics in other commonly used drug databases.
18.	Vetprofen	56	Veterinary product.
19.	Vetripen	60	Veterinary product.
20.	Viraferon	56	International product marketed in France, Czech Republic, Mexico, Netherlands, Portugal, Spain, UK, Ireland, and Poland.
21.	Viranol	58	Name identified in RxNorm and Red Book databases. Product is discontinued and no generic alternatives are available.
22.	Virazid	60	International product marketed in Italy, Australia, Indonesia, Mexico, and Spain.
23.	Vitravene	56	Name identified in RxNorm, Drugs At FDA, and Red Book databases. Product is discontinued and no generic alternatives are available.
24.	(b) (4) ***	56	Name identified in Names Entered by Safety Evaluator database. This name corresponds to NDA 021897, which was approved under the proprietary name, Vivitrol, on 4/13/2006.
25.	(b) (4) ***	60	(b) (4)

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

No.	Name	POCA Score (%)
1.	4-Terpineol, (+)-	60
2.	Bavencio***	64
3.	Benzepro	56
4.	Cardene Iv	58
5.	Ceresin	58
6.	Cerezyme	60
7.	Cervidil	58
8.	(b) (4) ***	55
9.	Degen Ii	58
10.	Dermoneen	58
11.	Doriden	55
12.	Duraphen Ii	56
13.	Fer-Gen-Sol	58
14.	Fernisone	56
15.	(b) (4) ***	60
16.	(b) (4) ***	55
17.	Jeridin	55
18.	Lorzone	55
19.	Nervine	57
20.	Paroven	56
21.	Perazine	56
22.	Pherazine Vc	55
23.	Profen Ii	60
24.	Pyrvinium	56
25.	Revatio	56
26.	Ser-A-Gen	56
27.	Serentil	55
28.	Serevent	58
29.	Serotonin	56
30.	Servisone	58
31.	Teargen Ii	60
32.	Terfenor	65
33.	Terizidone	58

[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

No.	Name	POCA Score (%)
34.	Terpineol	60
35.	Travenol	55
36.	Zefazone I.V.	55
37.	Zeranol	60
38.	Zeroxin	60
39.	Zerviate***	56
40.	Zirconium	56
41.	(b) (4) ***	56
42.	Zyrphen	56

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/s/

GRACE JONES
05/23/2017

CHI-MING TU
05/23/2017

CHI-MING TU on behalf of DANIELLE M HARRIS
05/26/2017