CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208855Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	December 1, 2017
Application Type and Number:	NDA 208855
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- 17397261
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to assess the proposed proprietary name, Verzenio, for NDA 208855.

1.1 BACKGROUND AND REGULATORY HISTORY

DMEPA previously reviewed and found the proprietary name Verzenio acceptable for abemaciclib tablets under NDA 208716.[a] Verzenio (abemaciclib) tablets, under NDA 208716, was approved on September 28, 2017 for the treatment of HR^+, $HER2^-$ advanced or metastatic breast cancer as a single agent following endocrine therapy and (b) (4) prior chemotherapy, or in combination with fulvestrant following endocrine therapy.

The Applicant submitted NDA 208855 for Verzenio (abemaciclib) tablets on August 15, 2017 for the treatment of HR^+, $HER2^-$ advanced or metastatic breast cancer in combination with aromatase inhibitor as initial endocrine-based therapy.

Eli Lilly submitted the proposed proprietary name, Verzenio, for NDA 208855 on September 5, 2017. We note that while there is a new indication for use proposed under NDA 208855, all other product characteristics remain the same.

2 METHODS AND DISCUSSION

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

For this assessment of the proposed proprietary name, DMEPA 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 proposed proprietary name. We also evaluated previously identified names taking into account the new proposed indication for use (see Table 1 for a comparison of the proposed indications).

Table 1. Comparison of the proposed indications between NDA 208855 and NDA 208716		
	Verzenio (NDA 208855) ***Source: 10/4/2017 submission[b]***	**Verzenio (NDA 208716)** ***Source: Drugs@FDA, accessed November 13, 2017[c]***

[a] Jones, G. Proprietary Name Review for Verzenio (IND 106100, NDA 208716). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAY 23. Panorama No. 2017-14018751 (IND 106100), 2017-14948718 (NDA 208716).

[b] Draft labeling submitted on October 4, 2017: \\cdsesub1\evsprod\nda208855\0004\m1\us\proposed-uspi-clean.docx

Table 1. Comparison of the proposed indications between NDA 208855 and NDA 208716		
	Verzenio (NDA 208855) ***Source: 10/4/2017 submission[b]***	**Verzenio (NDA 208716)** ***Source: Drugs@FDA, accessed November 13, 2017[c]***
Proposed Indications and Usage	• in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant (b) (4) for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. • as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.	• In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy • As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Besides the indication, all product characteristics under NDA 208855 are the same as the currently approved NDA 208716. The additional indication proposed for NDA 208855 does not preclude use of the proposed name, Verzenio, for this proposed product. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 13, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Furthermore, our FDA Adverse Event Reporting System (FAERS) database search did not identify any concerns with the proposed name, Verzenio (see Section 2.3). Thus, we do not object to the use of the proposed name, Verzenio, for NDA 208855.

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[c] Note that the Verzenio NDA 208716 PI from 8/31/2017 occurred after the first round of labeling negotiations. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208716Orig1s000lbl.pdf

2.3 MEDICATION ERROR DATA SELECTION OF CASES

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A for a description of FAERS database) for name confusion errors involving ***Verzenio*** that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	November 20, 2017
Drug Name	Verzenio [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms** **Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	None

Our FAERS search yielded no case reports.

2.4 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 November 27, 2017. At that time we also requested additional information or concerns that

could inform our review. The DOP1 did not provide any additional concerns with the proposed proprietary name, Verzenio.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact 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 September 5, 2017 submission 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.

Appendix A: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

GRACE JONES
12/01/2017

CHI-MING TU
12/01/2017