CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211225Orig1s000

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:	August 21, 2018
Application Type and Number:	NDA 211225
Product Name and Strength:	Zykadia (ceritinib) tablets, 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis Pharmaceuticals Corp
Panorama #:	2018-23574094
DMEPA Safety Evaluator:	Colleen Little, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, Pharm D

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Zykadia (ceritinib) capsules, 150 mg, were approved under NDA 205755 on April 29, 2014. The Applicant now seeks approval for the new dosage formulation, tablets, under NDA 211225. The Applicant submitted the proposed proprietary name, Zykadia, for review under NDA 211225 on June 5, 2018.

1.2 PRODUCT INFORMATION

Table 1 presents relevant product information provided in the proprietary name submission received on June 5, 2018 and from Zykadia capsules Prescribing Information approved on December 21, 2017[a].

Table 1: Relevant Product Information for Zykadia

Product Name	**Zykadia (proposed)**	**Zykadia (approved April 29, 2015)**
Intended Pronunciation	zye kaye' dee ah	zye kaye' dee ah
Active ingredient	ceritinib	ceritinib
Indication of Use	For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test	For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
Route of Administration	Oral	Oral
Dosage Form	Tablets	Capsules
Strength(s)	150 mg	150 mg
Dose and Frequency	450 mg (3 x 150 mg tablets) once daily with food	450 mg orally once daily with food until disease progression or unacceptable toxicity
How Supplied	Bottles for commercial use will contain 84 tablets. Physician sample bottles will contain 21 tablets.	Bottles of 70 capsules

[a] Zykadia [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. Dec 2017. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205755s010lbl.pdf.

Storage	Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)	Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F 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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 2 (DOP2) 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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Zykadia 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, June 19, 2018 e-mail, the Division of Oncology Products 2 (DOP2) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[b] USAN stem search conducted on June 14, 2018.

2.2.4 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 A1 for a description of FAERS database) for name confusion errors involving Zykadia that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	June 14, 2018
Drug Name	Zykadia [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	04/29/2014 to 06/01/2018

The search yielded no relevant cases related to name confusion with Zykadia.

2.2.5 Multiple Dosage Forms under a Single Proprietary Name

Zykadia is currently marketed under NDA 205755 as capsules in the strength of 150 mg. We considered the appropriateness of using the same proprietary name, Zykadia, for the newly

proposed 150 mg tablet formulation under NDA 211225. We note that the currently marketed Zykadia capsules and the proposed tablets share the same active ingredient, indication, route of administration, strength, dose, and frequency of administration.

Per the Applicant's June 5, 2018 request for proprietary name review submission, the proposed tablets are a bioequivalent replacement for the currently marketed capsules. We also note the Applicant stated in their June 5, 2018 submission, "Novartis does not plan to maintain both dosage forms on the US market. Once the capsule inventory is depleted from the US market (estimated by end of 2019), Zykadia will only be available as the film-coated tablet in the US." Provided that the DOP2 review team confirms these products are bioequivalent, we do not anticipate the Applicant's proposal to market both formulations with the same proprietary name will introduce any new medication errors during the transition period.

It is common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Moreover, we have not identified any medication errors involving name confusion with the proprietary name, Zykadia. Therefore, we find the Applicant's proposal to market the proposed product with the proprietary name Zykadia acceptable.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on August 8, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP2 on August 21, 2018, they stated no additional concerns with the proposed proprietary name, Zykadia.

3 CONCLUSION

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, Zykadia, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on June 5, 2018, 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.

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. [c]

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

Appendix A1: 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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