

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

212273Orig1s000

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:	August 22, 2019
Application Type and Number:	NDA 212273
Product Name and Strength:	Trikafta (elexacaftor/ tezacaftor/ivacaftor) Tablets 100 mg/50 mg/75 mg and 150 mg of ivacaftor
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Vertex Pharmaceuticals Inc
Panorama #:	2019-33248911
DMEPA Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Trikafta, which was found conditionally acceptable under IND (b) (4) on November 1, 2018.^a

We note that there is a change in strength (from (b) (4) to 100 mg/50 mg/75 mg and 150 mg) for NDA 212273. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Trikafta would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment for Trikafta.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 change in strength (from (b) (4) to 100 mg/50 mg/75 mg and 150 mg). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Trikafta.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The August 15, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Trikafta.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on August 22, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) on August 22, 2019, they stated no additional concerns with the proposed proprietary name, Trikafta.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Trikafta, is acceptable.

^a Abraham, Sherly. Proprietary Name Review for Trikafta (IND (b) (4)). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 NOV 01. Panorama No.: 2018- 23096373.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO VERTEX PHARMACEUTICALS INC

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

If any of the proposed product characteristics as stated in your submission, received on July 19, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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08/22/2019 12:24:43 PM

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