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RESEARCH**

APPLICATION NUMBER:

215413Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	November 5, 2021
Application Type and Number:	NDA 215413
Product Name and Strength:	Triumeq PD (abacavir, dolutegravir, and lamivudine) Tablet for Oral Suspension, 60 mg/5 mg/30 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
PNR ID #:	2021-1044724214
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Triumeq PD, which was found conditionally acceptable under IND (b) (4) on January 14, 2021.^a Thus, ViiV submitted the name, Triumeq PD, under NDA 215413 for review on October 1, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Triumeq PD would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Triumeq PD.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previous assessment of the proposed root name 'Triumeq' and the use of the modifier 'PD'. Our reassessment did not change our previous conclusion and we agree with the previous assessment of the proposed proprietary name Triumeq PD. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The October 23, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Triumeq PD.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Antivirals (DAV). At that time we also requested additional information or concerns that could inform our review. On November 5, 2021, the Division of Antivirals (DAV) stated no additional concerns with the proposed proprietary name, Triumeq PD.

3 CONCLUSION

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

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO ViiV HEALTHCARE COMPANY

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

^a Vaughan, V. Proprietary Name Review for Triumeq PD (IND 114820). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 JAN 14. PNR ID No. 2020-41507108.

If any of the proposed product characteristics as stated in your submission, received on October 1, 2021, 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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