CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211994Orig1s000

<u>PROPRIETARY NAME REVIEW(S)</u>

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:	January 7, 2019
Application Type and Number:	NDA 211994
Product Name and Strength:	Dovato (dolutegravir and lamivudine) Tablet, 50 mg/300 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Viiv Healthcare Company
Panorama #:	2018-26703530
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Teresa McMillan, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Dovato, which was found conditionally acceptable under IND 127475 on August 16, 2018.[a] We note that all product characteristics remain the same. The Applicant submitted an external name study, conducted by (b) (4), for this product, which was previously analyzed during the last review of this proprietary name.

2 METHODS AND DISCUSSION

2.1 Misbranding Assessment

The Office of Prescription Drug Promotion (OPDP) determined that Dovato would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antiviral Products (DAVP) concurred with the findings of OPDP's assessment for Dovato.

2.2 Safety Assessment

For re-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.

Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 9, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Dovato.

2.3 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antiviral Products (DAVP) via e-mail on December 20, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antiviral Products (DAVP) on December 26, 2018, they stated no additional concerns with the proposed proprietary name, Dovato.

3 CONCLUSIONS

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, Dovato, is acceptable.

If you have any questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3818.

3.1 Comments to ViiV Healthcare Company

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

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[a] Wilson, V. Proprietary Name Review for Dovato (IND 127475). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 16. Panorama No.: 2018-22206815.

If any of the proposed product characteristics as stated in your submission, received on October 18, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

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