CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212950Orig1s000

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:	February 5, 2020
Application Type and Number:	NDA 212950
Product Name and Strength:	Rukobia (fostemsavir) Tablets, Extended Release 600 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ViiV Healthcare Company (ViiV)
Panorama #:	2019-35884560
DMEPA Safety Evaluator:	Valerie S. Vaughan, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Rukobia, which was found conditionally acceptable under IND 073916 on November 1, 2019.[a]

Thus, ViiV submitted the name, Rukobia, under NDA 212950 for re-review on November 19, 2019. We note that there is a change in product storage. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

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 product storage. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Rukobia.

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 November 20, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Rukobia.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Antivirals (DAV) via e-mail on January 28, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antivirals (DAV) on February 5, 2020, they stated no additional concerns with the proposed proprietary name, Rukobia.

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, Rukobia, is acceptable.

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

[a] Vaughan, V. Proprietary Name Review for Rukobia (IND 073916). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 NOV 01. Panorama No.: 2019-33858616.

3.1 COMMENTS TO VIIV HEALTHCARE COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on November 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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02/05/2020 04:44:49 PM

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02/05/2020 04:46:23 PM