APPLICATION NUMBER:

210251Orig1s000

PROPRIETARY NAME REVIEW(S)
Date of This Review: August 22, 2017
Application Type and Number: NDA 210251
Product Name and Strength: Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide) Tablets 50 mg/200 mg/25 mg
Product Type: Multi-ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Gilead Sciences, Inc.
Panorama #: 2017-15786142
DMEPA Safety Evaluator: Nasim Roosta, PharmD
DMEPA Team Leader: Otto L. Townsend, PharmD
1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Biktarvy, which was found conditionally acceptable under IND 125589 on April 21, 2017. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 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 name contains any USAN stems as of the last USAN updates. The July 26, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 is acceptable.

If you have any questions or need clarifications, please contact Azeem D. Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 20, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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a Roosta, Nasim. Proprietary Name Review for Biktarvy IND 125589. Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); [2017 04 21]. Panorama No. 2016-12078984.
4 REFERENCES

   USAN Stems List contains all the recognized USAN stems.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NASIM N ROOSTA
08/22/2017

OTTO L TOWNESEND
08/22/2017