CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208215Orig1s000

PROPRIETARY NAME REVIEW(S)
Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Memorandum

Date: May 15, 2015
Reviewer: Mónica Calderón, PharmD, BCPS
Division of Medication Error Prevention and Analysis
Team Leader: Vicky Borders-Hemphill, PharmD
Division of Medication Error Prevention and Analysis
Drug Name and Strength: Descovy (emtricitabine, tenofovir alafenamide) Tablets,
200 mg/25 mg
Application Type/Number: NDA 208215
Applicant/Sponsor: Gilead
OSE RCM #: 2015-81085

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CONTENTS

1 INTRODUCTION ........................................................................................................................................ 3
2 METHODS AND DISCUSSION ........................................................................................................ 3
3 CONCLUSIONS .................................................................................................................................... 3
4 REFERENCES ......................................................................................................................................... 4
1 INTRODUCTION
This memorandum is to re-assess the proposed proprietary name, Descovy, under NDA 208215 submitted April 8, 2015. DMEPA previously found the name Descovy, acceptable for this product in OSE Review# 2014-1948 dated December 12, 2014 under IND 111851. All product characteristics remain the same.

2 METHODS AND DISCUSSION
For re-assessments of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database to identify names with high orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2014-1948. Additionally, 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. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The April 20, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. The Division of Antiviral Products (DAVP) concurred with OPDP’s assessment in an email dated May 12, 2015.

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

If you have further questions or need clarifications, please contact, OSE Project Manager, Danyal Chaudhry, at 301-796-3813

3.1 COMMENTS TO THE APPLICANT/SPONSOR
We have completed our review of the proposed proprietary name, Descovy, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 8, 2015 submission are altered, the name must be resubmitted for review.
4 REFERENCES


   USAN Stems List contains all the recognized USAN stems.

3. **Phonetic and Orthographic Computer Analysis (POCA)**

   POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MONICA M CALDERON
05/15/2015

BRENDA V BORDERS-HEMPHILL
05/15/2015