CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208351Orig1s000

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:	July 24, 2015
Application Type and Number:	NDA 208351
Product Name and Strength:	Odefsey (emtricitabine, rilpivirine, tenofovir alafenamide) Tablets, 200 mg/25 mg/25 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gilead Sciences, Inc.
Panorama #:	2015-887608
DMEPA Primary Reviewer:	Mónica Calderón, PharmD, BCPS
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Odefsey. DMEPA previously found this name acceptable in OSE Review # 2014-45072, under IND 123098, dated March 17, 2015.

1.1 PRODUCT INFORMATION

The following product information is provided in the July 2, 2015 proprietary name submission.

- Intended Pronunciation: oh-DEF-see
- Active Ingredient: emtricitabine, rilpivirine, tenofovir alafenamide
- Indication of Use: treatment of HIV-1 infection in (b) (4) patients with no antiretroviral treatment history and with HIV-1 RNA less than or equal to 100,000 copies/mL (b) (4), or who are virologically-suppressed on a stable regimen with no resistance to the components of F/R/TAF.
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 200 mg/25 mg/25 mg
- Dose and Frequency: One tablet once daily
- How Supplied: 30-count bottles.
- Storage: (b) (4) (b) (4)

1.2 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

1.3 SAFETY ASSESSMENT

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 3) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review # 2014-45072 that have orthographic and phonetic similarities to the proposed name Odefsey. Our POCA search did not identify any new names that represent a potential source of drug name confusion.

We re- 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. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 10, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Lastly, we reviewed the product characteristics in the current proprietary name submission and compared them to the product characteristics in the previous proprietary name review. We determined that none of the product characteristics have changed since the last proprietary name review.

As a result, we maintain that the name, Odefsey, is acceptable.

2 CONCLUSIONS

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

If any of the proposed product characteristics as stated in your July 2, 2015 submission are altered, the name must be resubmitted for review.

If you have further questions or need clarifications, please contact Danyal Chaudhry OSE project manager at 301-496-3813.

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/s/

MONICA M CALDERON
07/24/2015

BRENDA V BORDERS-HEMPHILL
07/24/2015