# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 208341Orig1s000

# PROPRIETARY NAME REVIEW(S)

**PROPRIETARY NAME REVIEW**

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*****

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|---|---|
| **Date of This Review:** | January 8, 2016 |
| **Application Type and Number:** | NDA 208341 |
| **Product Name and Strength:** | Epclusa<br>(sofosbuvir and velpatasvir) Tablets<br>400 mg/100 mg |
| **Product Type:** | Multi-Ingredient Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Gilead Sciences, Inc. |
| **Panorama #:** | 2015-1886182 |
| **DMEPA Primary Reviewer:** | Mónica Calderón, PharmD, BCPS |
| **DMEPA Team Leader:** | Vicky Borders-Hemphill, PharmD |

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Epclusa, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

## 1.1 PRODUCT INFORMATION

The following product information is provided in the October 30, 2015 proprietary name submission.

- Intended Pronunciation: ep-KLOO-suh
- Active Ingredient: sofosbuvir and velpatasvir
- Indication of Use: Treatment of chronic hepatitis C infection
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 400 mg/100 mg
- Dose and Frequency: one tablet once daily
- How Supplied: 28-count bottles
- Storage: At or below 30˚C

# 2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

## 2.1 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 Antiviral Products (DAVP) concurred with the findings of OPDP's assessment of the proposed name.

## 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

### *2.2.1 United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary name[1].

[1]USAN stem search conducted on December 2, 2015.

### *2.2.2 Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Epclusa in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

### *2.2.3 FDA Name Simulation Studies*

Sixty-five practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Thirty-two participants correctly identified the name. Fifteen participants misinterpreted the letter 's' for the letter 'r' (n= 15 outpatient). Appendix B contains the results from the verbal and written prescription studies.

### *2.2.4 Comments from Other Review Disciplines at Initial Review*

In response to the OSE, November 13, 2015 e-mail, the Division of Antiviral Products (DAVP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### *2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the (b) (4) external name study.

| **Table 1. POCA Search Results** | **Number of Names** |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥50% to ≤ 69% | 42 |
| Low similarity name pair:<br>combined match percentage score ≤49% | 7 |

### *2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities*

Our analysis of the 50 names contained in Table 1 and determined none of the names will pose a risk for confusion as described in Appendices C through H.

[2] POCA search conducted on December 2, 2015.

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