CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214187Orig1s000

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*****

Date of This Review:	March 2, 2021
Application Type and Number:	NDA 214187
Product Name and Strength:	Epclusa (sofosbuvir and velpatasvir) oral pellets, 200 mg/50 mg and 150 mg/37.5 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Sciences
Panorama #:	2020-44675936
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

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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 proprietary name are outlined in the reference section and Appendix A respectively. Gilead submited an external name study for this proposed proprietary name that was previously reviewed by DMEPA.

1.1 REGULATORY HISTORY

Epclusa (sofosbuvir and velpatasvir) tablet was approved on June 28, 2016 under NDA 208341 for the treatment of adult patients with chronic hepatitis C virus infection.

Gilead is pursuing a oral pellet formulation in patients 3 years and older, therefore submitted the name, Epclusa, for review under NDA 214187 on December 15, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 15, 2020.

Table 1. Relevant product information for Epclusa Pellets and Epclusa tablet[a]

	Epclusa Pellets	Epclusa tablet
Initial Approval Date	N/A	June 28, 2016
Intended Pronunciation	Ep-KLOO-suh	
Active Ingredient	sofosbuvir and velpatasvir	
Indication	EPCLUSA is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.	EPCLUSA is indicated for the treatment of adults and pediatric patients 6 years of age and older or weighing at least 17 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.
Route of Administration	Oral	
Dosage Form	Oral pellets	Oral tablets
Strength	150 mg/37.5 mg and 200 mg/50 mg	200 mg/50 mg and 400 mg/100 mg

[a] Epclusa Product information obtained at https://dailymed nlm nih.gov/dailymed/drugInfo.cfm?setid=7f30631a-ee3b-4cfe-866b-964df3f0a44f Accessed February 18, 2021.

Dose and Frequency	**Recommended Dosage in Pediatric Patients 3 Years and Older** Less than 17 kg- One 150 mg/37.5 mg packet of pellets once daily 17 kg to less than 30 kg- One 200 mg/50 mg tablet or one 200 mg/50 mg packet of pellets once daily. At least 30 kg- One 400 mg/100 mg tablet (or two 200 mg/50 mg tablets or two 200 mg/50 mg packets of pellets) once daily	**Recommended Dosage in Adult and Pediatric Patients 6 Years and Older or Weighing at Least 17 kg** 17 kg to less than 30 kg- One 200 mg/50 mg tablet once daily 30 kg and up- One 400 mg/100 mg tablet (or two 200 mg/50 mg tablets) once daily
(How Supplied	Cartons of 28 packets	Bottles of 28 tablets
Storage	Store below 30°C (86°F)	

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Epclusa 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 Epclusa.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Epclusa.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Gilead did not provide a derivation or intended meaning for the proposed proprietary name, Epclusa, in their submission. This proprietary name is comprised of a single word that does not

[b] USAN stem search conducted on November 30, 2020.

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