CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204671Orig1s000

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 Review

Date:	November 6, 2013
Reviewer:	Morgan Walker, PharmD, MBA Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	(b) (4) (sofosbuvir) Tablets, 400 mg
Application Type/Number:	NDA 204671
Applicant/Sponsor:	Gilead
OSE RCM #:	2013-1881

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, (b) (4) from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Sovaldi, for IND 106739. However, during review of the proposed name Sovaldi, DMEPA determined that the name was unacceptable and communicated the following to the Applicant:

> "We conclude that the proposed proprietary name Sovaldi could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Sovaldi, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name of Sovaldi, you will be requested to submit another name." (OSE Review #2013-498, dated July 11, 2013).

The Applicant submitted an alternate name, (b) (4), for request for proprietary name review for NDA 204671 on August 16, 2013, thus the purpose of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 16, 2013 proprietary name submission.

- Active ingredient: sofosbuvir
- Indication: Used in combination with either ribavirin alone, or ribavirin and peginterferon alfa, for the treatment of chronic hepatitis C in adults.
- Route: Oral
- Dosage Form: Tablet
- Strengths: 400 mg
- Dose and Frequency: One tablet once daily
- How Supplied: Bottles of 28 tablets
- Storage: Room Temp.

2 RESULTS

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

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/s/

MORGAN A WALKER
11/06/2013

CAROL A HOLQUIST
11/06/2013