CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205834Orig1s000

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:	April 29, 2014
Requesting Office or Division:	Division of Antiviral Products (DAVP)
Application Type and Number:	NDA 205834
Product Name and Strength:	Harvoni (Ledipasvir and Sofosbuvir) Tablets 90 mg/400 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gilead Sciences
Submission Date:	02/28/2014
Panorama #:	2014-17039
DMEPA Primary Reviewer:	James Schlick, RPh, MBA
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

1 INTRODUCTION

The proposed proprietary name, Harvoni, was found acceptable in OSE review # 2013-2662, dated February 7, 2014 under IND 115268. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Harvoni, is acceptable from both a promotional and safety perspective under the NDA 205834.

If you have further questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your February 28, 2014 submission are altered, the name must be resubmitted for review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JAMES H SCHLICK
04/29/2014

IRENE Z CHAN
04/29/2014