CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212480Orig1s000

OTHER REVIEW(S)

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: 8/15/19

To: Philip Villasurda
Regulatory Project Manager
Division of Antiviral Products (DAVP)

From: Nima Ossareh, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sam Skariah, Team Leader, OPDP

Subject: OPDP Labeling Comments for HARVONI® (ledipasvir and sofosbuvir) tablets, for oral use, HARVONI® (ledipasvir and sofosbuvir) oral granules, SOVALDI® (sofosbuvir) tablets, for oral use, and SOVALDI® (sofosbuvir) oral granules

NDA/BLA: 205834/Supplement 29 and 212477 204671 Supplement 14

In response to DAVP consult request dated March 19, 2019, OPDP has reviewed the proposed product labeling (PI) and patient package insert (PPI) for HARVONI® (ledipasvir and sofosbuvir) tablets, for oral use, HARVONI® (ledipasvir and sofosbuvir) oral granules, SOVALDI® (sofosbuvir) tablets, for oral use, and SOVALDI® (sofosbuvir) oral granules. These supplements revise the label to provide information on the efficacy in patients 3 years of age and older.

PI: OPDP's comments on the proposed labeling are based on the draft PI and PPI received by electronic mail from Division of Antiviral Products (DAVP) on August 12, 2019 and are provided below.

PPI: A combined OPDP and Division of Medical Policy Programs (DMPP) review of the PPI will be completed under a separate cover.

Thank you for your consult. If you have any questions, please contact Nima Ossareh at (240) 402-2769 or nima.ossareh@fda.hhs.gov.

88 Page(s) of Draft Labeling have been Withheld in Full as b4

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NIMA OSSAREH
08/15/2019 04:01:08 PM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	August 13, 2019
To:	Debra Birnkrant, MD Director **Division of Antiviral Products (DAVP)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Nima Ossareh PharmD, RAC Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)** Morgan Walker, PharmD, MBA, CPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	SOVALDI (sofosbuvir)
Dosage Form and Route:	oral granules
Application Type/Number/ Supplement Number:	NDA 212480 and NDA 204671/S-014
Applicant:	Gilead Sciences, Inc.

1 INTRODUCTION

On February 28, 2019, Gilead Sciences, Inc. submitted for the Agency's review an original New Drug Application (NDA) 212477 for SOVALDI (sofosbuvir) oral granules. This original NDA references NDA 204671/S-014 SOVALDI (sofosbuvir) tablets. This application is intended to support the approval to market SOVALDI (sofosbuvir) oral granules for use in the treatment of hepatitis C virus (HCV) infection in pediatric patients.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Antiviral Products (DAVP) on March 28, 2019 for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for SOVALDI (sofosbuvir) oral granules.

2 MATERIAL REVIEWED

- Draft SOVALDI (sofosbuvir) oral granules PPI received on February 28, 2019, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on August 2, 2019.
- Draft SOVALDI (sofosbuvir) oral granules Prescribing Information (PI) received on February 28, 2019, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on August 2, 2019.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

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