

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### ***APPLICATION NUMBER:***

**212480Orig1s000**

***Trade Name:*** SOVALDI 150 mg and 200 mg oral pellets

***Generic or Proper Name:*** Sofosbuvir

***Sponsor:*** Gilead Sciences, Inc.

***Approval Date:*** August 28<sup>th</sup>, 2019

***Indication:*** For the treatment of chronic hepatitis C virus (HCV), genotypes 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis in combination with ribavirin.

# CENTER FOR DRUG EVALUATION AND RESEARCH

## 212480Orig1s000

### CONTENTS

|                                                           |
|-----------------------------------------------------------|
| <b>Reviews / Information Included in this NDA Review.</b> |
|-----------------------------------------------------------|

|                                                                                                                                                                                                                                                                                                                     |          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| <b>Approval Letter</b>                                                                                                                                                                                                                                                                                              | <b>X</b> |
| <b>Other Action Letters</b>                                                                                                                                                                                                                                                                                         |          |
| <b>Labeling</b>                                                                                                                                                                                                                                                                                                     | <b>X</b> |
| <b>REMS</b>                                                                                                                                                                                                                                                                                                         |          |
| <b>Officer/Employee List</b>                                                                                                                                                                                                                                                                                        | <b>X</b> |
| <b>Multidiscipline Review(s)</b> <ul style="list-style-type: none"><li>• <b>Summary Review</b></li><li>• <b>Office Director</b></li><li>• <b>Cross Discipline Team Leader</b></li><li>• <b>Clinical</b></li><li>• <b>Non-Clinical</b></li><li>• <b>Statistical</b></li><li>• <b>Clinical Pharmacology</b></li></ul> | <b>X</b> |
| <b>Product Quality Review(s)</b>                                                                                                                                                                                                                                                                                    | <b>X</b> |
| <b>Clinical Microbiology / Virology Review(s)</b>                                                                                                                                                                                                                                                                   | <b>X</b> |
| <b>Other Reviews</b>                                                                                                                                                                                                                                                                                                | <b>X</b> |
| <b>Risk Assessment and Risk Mitigation Review(s)</b>                                                                                                                                                                                                                                                                |          |
| <b>Proprietary Name Review(s)</b>                                                                                                                                                                                                                                                                                   |          |
| <b>Administrative/Correspondence Document(s)</b>                                                                                                                                                                                                                                                                    |          |

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**212480Orig1s000**

**APPROVAL LETTER**



NDA 212480

**NDA APPROVAL**

Gilead Sciences, Inc.  
Attention: Xiaoping Qi, M.S., RAC  
Associate Director, Regulatory Affairs  
333 Lakeside Drive  
Foster City, CA 94404

Dear Ms. Qi:

Please refer to your new drug application (NDA) dated and received on February 28, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SOVALDI (sofosbuvir) oral pellets, 150 mg and 200 mg.

This new drug application provides for the following:

- The use of SOVALDI (sofosbuvir) 150 mg and 200 mg oral pellets for the treatment of chronic hepatitis C virus (HCV), genotypes 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis in combination with ribavirin.
- To make corresponding changes to the Patient Information

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Prescribing Information and Patient Package Insert) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 212480.**” Approval of this submission by FDA is not required before the labeling is used.

### **MARKET PACKAGE**

Please submit one market package of the drug product when it is available to the following address:

CAPT Anitra Johnson, DHSc, MSN, RN  
Food and Drug Administration  
Center for Drug Evaluation and Research  
White Oak Building 22, Room: 6362  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
Use zip code **20903** if shipping via United States Postal Service (USPS).  
Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

---

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

We are waiving the pediatric study requirement from birth to 3 years of age because necessary studies are impossible or highly impracticable. This is due to a high rate of spontaneous HCV clearance resulting in very few patients requiring treatment in this age group.

This product is appropriately labeled for the use in ages 12 to 17 years of age for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 3 to less than 12 years for this application.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information, Medication Guide, and Patient Package Insert (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>3</sup>

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup> For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.<sup>6</sup>

---

<sup>3</sup> When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

<sup>6</sup> <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CAPT Anitra Johnson, DHSc, MSN, RN, Regulatory Project Manager, at 301-796-4876.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, MD  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and  
Research

### **ENCLOSURE(S):**

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Carton and Container Labeling

-----  
**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/  
-----

DEBRA B BIRNKRANT  
08/28/2019 12:55:22 PM