NDA 204671/S-018

SUPPLEMENT APPROVAL

Gilead Sciences Inc.
Attention: Solmaz Dehghan, PharmD, PhD
Manager, Regulatory Affairs, CMC
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Dehghan:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 28, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sovaldi (sofosbuvir) Tablets, 200 mg.

This "Changes Being Effected" supplemental new drug application provides for the revision of the container label of Sovaldi (Sofosbuvir) tablets, 200 mg, to provide consistency between the container label and prescribing information. The revised label includes the following modifications:

- The dosing statement "Take 1 tablet once daily" will be removed from the principal display panel of the container label.
- The current dosing statement "See package insert for dosage and administration." on the side panel of container label will be replaced with the statement "Recommended dosage: See prescribing information."

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on August 26, 2020, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 204671/S-018.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Omolara Laiyemo, Regulatory Business Process Manager, at (240) 402 - 3842.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Container Labeling

David Lewis

Digitally signed by David Lewis
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