DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205834/S-11

APPROVAL LETTER

Gilead Sciences, Inc.
Attention: Prachi Shah, MBS, RAC
Associate Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated December 11, 2015, received December 11, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Harvoni® (ledipasvir/sofosbuvir), tablet, 90 mg/400 mg.

This Changes Being Effected supplemental new drug application proposes the following change:

- To revise the container label to include text "Take 1 tablet once daily"

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mammah Sia Borbor, Regulatory Project Manager, at (301) 796-7731 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

JEFFREY S MURRAY
02/17/2016