



NDA 208341/S-020

SUPPLEMENT APPROVAL

Gilead Sciences Inc.
Attention: George Burlingame
Senior Associate, Regulatory Affairs, CMC
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. Burlingame:

Please refer to your Supplemental New Drug Application (sNDA) dated June 22, 2022, received June 22, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epclusa (sofosbuvir and velpatasvir) Tablets, 400 mg/100 mg.

We also refer to our approval letter dated December 14, 2022, which contained the following error: *The phrase "a primary packaging and drug product release site" was erroneously stated as "alternate primary packaging and release testing site" in the 'provides for' statement.*

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 14, 2022, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of Gilead Sciences Inc., La Verne, CA, FEI: 3013189568, as a primary packaging and drug product release site for Epclusa tablets, 400 mg/100 mg.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 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, Ph.D.
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



David
Lewis

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