NDA 208464/S-015

SUPPLEMENT APPROVAL

Gilead Sciences Inc
Attention: Laura Morley
Manager, Regulatory Affairs, CMC
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Morley:

Please refer to your Supplemental New Drug Application (sNDA) dated June 20, 2022, received June 21, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vemlidy (Tenofovir Alafenamide) Tablets, 25 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 addition of Gilead Sciences Inc., La Verne, CA, FEI: 3013189568 as a primary packaging and drug product release site for VEMLIDY tablets.

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

Digitally signed by David Lewis
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