



NDA 208215/S-014

APPROVAL LETTER

Gilead Sciences Inc.
Attention: Kate Lawrence
Manager Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Lawrence:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 26, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Descovy (emtricitabine and tenofovir alafenamide) Tablets, 200 mg /25 mg.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the addition of a new seven-count blister packaging configuration for Descovy tablets intended for physician/professional samples

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 carton and container labels submitted on May 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 208215/S-014.**” Approval of this submission by FDA is not required before the labeling is used.

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

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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

Enclosures:

Carton and Container Labeling



David
Lewis

Digitally signed by David Lewis
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