NDA 210251/S-017

**SUPPLEMENT APPROVAL**

Gilead Sciences, Inc.
Attention: Shweta Patel
Senior Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Patel:

Please refer to your supplemental new drug application (sNDA) dated and received on March 3, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide; B/F/TAF) Tablets.

This Prior Approval sNDA responds to a February 2, 2023, Prior Approval Supplement Request from the FDA to update the Biktarvy container labeling to provide for better visual differentiation between the Biktarvy (B/F/TAF) adult strength tablets (50 mg/200 mg/25 mg) from the Biktarvy (B/F/TAF) low-strength tablets (30 mg/120 mg/15 mg) tablets.

## APPROVAL & LABELING

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

## CARTON AND CONTAINER LABELING

Submit final printed container labeling that are identical to the container labeling submitted on March 3, 2023, for the Biktarvy (B/F/TAF) adult strength tablets (50 mg/200 mg/25 mg) and on April 12, 2023, for the Biktarvy (B/F/TAF) low-dose tablet (30 mg/120 mg/15 mg) as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 Labeling for approved NDA 210251/ S-017**." Approval of this submission by FDA is not required before the labeling is used.

**PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, contact Suzanne Strayhorn, Regulatory Project Manager, at (240) 402-4247 or (301) 796-1500.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Container Labels

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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POONAM MISHRA
05/01/2023 11:34:30 AM
on behalf of Division Director