NDA 210251 02 .

PPROV L LETTER

Gilead ciences, Inc
Attention: Cristiana Zaharia
Director, CMC Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Cristiana Zaharia:

Please refer to your upplemental New Drug Application (sNDA) dated and received October 15, 2025, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide) tablets

This "Changes Being Effected in 30 days" supplemental new drug application provides for the introduction of a new 10 count blister packaging configuration and associated labeling changes

PPROV L & L BELING

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

We note that your October 15, 2025, submission includes final printed labeling (FPL) for your prescribing information, and patient package insert We have not reviewed this FPL You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (PL) format

CONTENT OF L BELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314 50(l)] in structured product labeling (PL) format using the FDA automated drug registration and listing system (eLI T), as described at http: www fda gov ForIndustry Data tandards tructuredProductLabeling default htm Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and text for the patient package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling

Information on submitting PL files using eLI T may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

http: www.fda.gov downloads DrugsGuidanceComplianceRegulatoryInformation Guidances UCM072392.pdf.

The L will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in M S Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked up copy that shows all changes, as well as a clean Microsoft Word version. The marked up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

We acknowledge your January 14, 202 , submission containing final printed carton and container labeling.

PATENT LISTING REQUIREMENTS

ursuant 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).

REPORTING REQUIREMENTS

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

COMPENDIAL STANDARDS

A drug with a name recognized in the official United tates harmacopeia or official s National Formulary (U NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 U C 351(b)). FDA typically cannot share application specific information contained in submitted regulatory filings with third parties, which includes U NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with U NF to revise s

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If you have any questions, contact Emma Gimose, Regulatory Business rocess Manager, at emma.gimose@fda.hhs.gov or (240) 402 1 81.

incerely,

{See appended electronic signature page}

Nina Ni, hD **s**
upervisor
Division of roduct Quality Assessment VII **s**
Office of roduct Quality Assessment II
Office of harmaceutical Quality
Center for Drug Evaluation and Research

[1] https: www.uspnf.com/ **s**

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