DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-752/S-002

Gilead Sciences, Inc.
Attn: Dean Waters
Associate Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. Waters:

Please refer to your supplemental new drug application dated February 11, 2005, received February 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Truvada® (emtricitabine/tenofovir DF) Tablets. We also acknowledge receipt of your submission dated March 8, 2005.

This "Changes Being Effected" supplemental new drug application provides for revised wording for the **INDICATIONS and USAGE** and **Description of Clinical Studies** sections of the Truvada label as outlined in our January 7, 2005 CBE Supplement Request Letter. In addition to several minor editorial changes, the supplement provided for correction of the following:

- The confidence interval information reported for the AUC and Cmin of lopinavir/ritonavir provided in Table 4 of the PI was changed. The lower bound of the confidence interval for AUC has been changed from 26 to 25 and the lower bound of the confidence interval for Cmin has been changed from 32 to 37.

- The information reported for the Cmin of emtricitabine provided in Table 5 of the PI was changed from ↔ to ↑ 20 (↑ 12 to ↑ 29).

- Grade ¾ elevations of serum amylase has been changed from "serum amylase (> 5x ULN)" to serum amylase (> 2 x ULN)". The upper limit of normal for serum amylase was identified as 88 U/L by the laboratory performing this test for study protocol GS-99-903.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 11, 2005.

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, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Attachments: Package Insert and Patient Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Debra Birnkrant
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NDA 21-752