



NDA 21-752/S-006

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 June 7, 2005, received June 8, 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 August 16, 2005 and received on August 17, 2005.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the Truvada label:

1. The addition of 144-Week clinical data from Study 903 into the Truvada Package Insert. These data were previously submitted on June 4, 2004 to the Viread NDA 21-356, approved on May 12, 2005. Incorporation of these data revises the **Antiviral Activity, Resistance, Description of Clinical Studies, and Precautions** sections of the Truvada Package Insert.
2. Revisions to **Post Marketing Experience, Viread** section. The text "increased amylase" and "increased liver enzymes" were deleted from this section since they are already listed in the **Adverse Reactions, Clinical Trials, Viread** section.
3. The addition of an **Immune Reconstitution Syndrome** section under **PRECAUTIONS**.

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 August 16, 2005 and received on August 17, 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) 796-0777.

Sincerely,

{See appended electronic signature page}

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

Attachments: Package Insert and Patient Package Insert – final printed labeling.

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

/s/

Jeffrey Murray
10/5/2005 11:20:03 AM