



NDA 21356/S-006

Gilead Sciences, Inc
Attention: Alan S. Taylor, PhD
Vice President, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Taylor:

Please refer to your supplemental new drug application dated May 1, 2003, received, May 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIREAD[®] (tenofovir disoproxil fumarate) 300mg Tablets.

We acknowledge receipt of your submissions dated May 29, 2003, June 13, 2003, August 20, 2003, August 21, 2003, and August 22, 2003, and received May 30, 2003, June 16, 2003, August 21, 2003, August 22, 2003, and August 25, 2003, respectively.

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

This supplemental new drug application (SLR-006) provides for the following revisions to the safety information in the VIREAD[®] professional package insert (PI) and patient package insert (PPI):

1. Addition of one paragraph in the Pharmacokinetics, Special Populations section about the pharmacokinetics of tenofovir in non-HIV infected patients with moderate to severe hepatic impairment.
2. Removal of the Hepatic Impairment paragraph from the PRECAUTIONS section.
3. Addition of emtricitabine to the list of drugs that, in combination with VIREAD[®], have been studied in healthy volunteers.
4. Addition of emtricitabine in Table 2 to reflect most current study data.
5. Addition of emtricitabine in Table 3 to reflect most current study data.
6. Addition of the following sentence in the HOW SUPPLIED section and the Patient Package Insert: "Do not use if seal over bottle opening is broken or missing."
7. Update of the revision date to October 2003 in both the PI and PPI.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) dated October 30, 2003.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 21-356/S-006**". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Marsha S. Holloman, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Final Printed Labeling (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/

Jeffrey Murray
10/31/03 03:47:41 PM