



NDA 21356/S-005

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 March 19, 2003, received, March 20, 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 March 28, 2003, April 3, 2003, June 13, 2003, and August 21, 2003, and received March 31, 2003, April 4, 2003, June 16, 2003, and August 22, 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-005) provides for the following revisions to the safety information in the VIREAD[®] professional package insert:

1. Addition of methadone to the list of drugs that, in combination with VIREAD[®], have been evaluated in healthy volunteers.
2. Revision of the lopinavir/ritonavir (KALETRA) entry in Table 2 to reflect most current study data.
3. Addition of information indicating the lack of clinically significant drug interactions between methadone maintenance therapy or oral contraceptives and VIREAD.
4. Revisions to the lopinavir and the ritonavir entries and addition of methadone entry in Table 3 to reflect most current study data.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) dated August 21, 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-005**". 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/

Debra Birnkrant
10/14/03 11:51:56 AM
NDA 21-356