DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-356

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 December 17, 2003, received December 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIREAD (tenofovir disoproxil fumerate) 300 mg Tablets.

We acknowledge receipt of your submission dated June 28, 2004.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), and include the following changes:

1. Addition of a boxed warning regarding use in HBV/HIV coinfected patients and inclusion of similar language in the Warnings section. The spelling of "coinfected" was corrected.

2. Pharmacokinetics section: addition of adefovir dipivoxil and ribavirin in the text and tables and addition of precautionary wording regarding drug interaction between VIREAD/atazanavir and lopinavir/ritonavir.

3. Carcinogenesis, Mutagenesis, Impairment of Fertility section - addition of language based on long-term carcinogenicity studies.

4. Updated registered trademark information.

The final printed labeling (FPL) must be identical, to the enclosed labeling (text for the package insert) submitted June 28, 2004.

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-010". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your ongoing postmarketing study committments.

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

Please submit one market package of the drug product when it is available.

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 Hollomanm, 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
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure: 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
7/1/04 04:19:20 PM
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