DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-356/S-021
NDA 21-752/S-011

Gilead Sciences, Inc.
Attention: Pamela L. Danagher, M.Sc.
Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Danagher:

Please refer to your supplemental new drug applications dated November 1, 2006, received November 2, 2006, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Viread® (tenofovir disoproxil fumarate) and Truvada® (emtricitabine/tenofovir disoproxil fumarate).

We acknowledge receipt of your submissions dated November 28, 2006, April 25, 2007, May 7, 2007 and May 9, 2007.

These supplemental new drug applications provide for the following changes:

1. Changes to the Boxed Warning section regarding the potential for exacerbation of hepatitis B following the cessation of treatment with tenofovir DF
2. Changes to information regarding product use and renal impairment including revisions to the WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections of the label
3. Changes based upon recent revisions to the company core safety information for Viread and Truvada, including proposed revisions to the *Post Marketing Experience* section
4. Streamlining of the Adverse Reactions, Clinical Trial section (Truvada label)

We completed our review of these applications, as amended. These applications are 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, text for the patient package insert). Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Include content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-356/S-021, NDA 21-752/S-011**." Approval of these submissions 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Holloman, Regulatory Project Manager, at (301) 796-0731.

Sincerely,

{See appended electronic signature page}

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

Enclosures (clean copy of PI/PPI for Viread and Truvada)

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
5/21/2007 04:56:08 PM
NDA 21-356, 21-752