



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-356/S-017

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 May 27, 2005, received May 31, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIREAD<sup>®</sup> (tenofovir disoproxil fumarate, TDF) 300 mg Tablets.

We acknowledge receipt of your submissions dated November 9, November 17, and November 21, 2005.

This supplemental new drug application provides for revisions to the package insert to add information to the Pharmacokinetics, Drug Interactions section based on data from two final study reports for Study GS-US-104-0236 and study GS-US-104-0237. Specifically, nelfinavir and saquinavir/ritonavir were added to the list of drugs that have been evaluated in healthy volunteers in combination with VIREAD<sup>®</sup>.

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) submitted November 21, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-356/S-017**". 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  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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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 Health Project Manager, at (301) 796-0371.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert Final Agreed-upon Labeling

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

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Debra Birnkrant  
11/30/2005 03:41:02 PM  
NDA 21-356