



NDA 21-356/S-026

GILEAD SCIENCES, INC.

Attention: Dara Wambach, M.A.  
Senior Manager, Regulatory Affairs  
333 Lakeside Drive  
Foster City, CA 94404

Dear Ms. Wambach:

Please refer to your supplemental new drug application dated March 19, 2008, received March 20, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viread<sup>®</sup> (tenofovir disoproxil fumarate) Tablets.

We acknowledge receipt of your submissions dated June 18, 2008, July 16, 2008, August 27, 2008, September 17, 2008 and September 26, 2008.

This supplemental new drug application provides for labeling revisions to the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, Post Marketing Experience and PATIENT COUNSELING INFORMATION, FDA-Approved Patient Labeling sections of the Full Prescribing Information.

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 enclosed agreed-upon labeling text.

#### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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> that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. **For administrative purposes, please designate this submission, "SPL for approved NDA 21-356/S-026."**

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

#### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see [www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac).

### **LETTERS TO HEALTH CARE PROFESSIONALS**

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

MedWatch  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

### **REPORTING REQUIREMENTS**

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 Elizabeth Thompson, MS, Regulatory Project Manager, at (301) 796-0824.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure (clean copy of approved label)

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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  
11/4/2008 09:44:38 AM  
NDA 21-356