



NDA 21-500/S-003

Gilead Sciences, Inc.  
Attn: Dara Wambach, MA  
Associate Manager, Regulatory Affairs  
333 Lakeside Drive  
Foster City, CA 94404

Dear Ms. Wambach:

Please refer to your new drug application dated June 1, 2005, received June 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMTRIVA<sup>®</sup> (emtricitabine) 200mg Capsules.

We acknowledge receipt of your submissions dated June 1, 2005 and received June 2, 2005.

This supplemental new drug application provides for revisions to the package insert to add information to the Clinical Pharmacology section to update NDA 21-500 so that it coincides with the labeling approved September 28, 2005 for NDA 21-896 EMTRIVA<sup>®</sup> Solution. Specifically, this submission provides for the following labeling changes:

1. Revision of the Clinical Pharmacology section to include results from pharmacokinetics Study 115 regarding coadministration of emtricitabine/zidovudine.
2. Revisions of the Precautions section:
  - Drug Interactions section updated to include results from pharmacokinetics Study 115 regarding coadministration of emtricitabine/zidovudine.
  - Addition of a new section entitled "Immune Reconstitution Syndrome".
  - Carcinogenesis section updated to include results of completed rat and mouse carcinogenicity studies

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 patient package insert) submitted to NDA 21-896 and approved September 28, 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 21-500/S-003**". 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

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) 796-0731.

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  
12/2/2005 03:45:58 PM  
NDA 21-500