



NDA 21-500

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

Please refer to your supplemental new drug application dated February 14, 2005, received February 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emtriva® (emtricitabine) 200 mg Capsules.

This “Changes Being Effected in 30 days” supplemental new drug application provides for inclusion of a class warning in the **Black Box Warning** and **Warnings** sections of the Package Insert regarding the potential for exacerbation of Hepatitis B following cessation of antiretroviral treatment. In addition, minor editorial changes were made to the Package Insert and Patient Package Insert. This supplement was submitted in response to the Division’s January 14, 2005 Supplement Request Letter. In addition, we refer to your submission dated June 7, 2004 requesting authorization to modify the wording proposed by the Division in our Supplemental Request Letter. We also refer to our September 24, 2004 facsimile agreeing to your proposed revision.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted with this supplement.

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Jeffrey Murray  
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