CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-896

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-896

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 March 29, 2005, received March 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMTRIVA (emtricitabine) Oral Solution.

We acknowledge receipt of your submissions dated:

April 14, 2005	July 28, 2005
April 15, 2005	August 1, 2005
April 25, 2005	August 15, 2005
April 28, 2005	September 1, 2005
June 9, 2005	September 9, 2005
July 8, 2005	September 12, 2005
July 25, 2005	September 13, 2005
	September 22, 2005

This new drug application provides for the use of EMTRIVA® (emtricitabine) Oral Solution, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in patients over three months of age.

We have completed our review of this application, as amended. It 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, text for the patient package insert, and immediate container and carton labels) submitted September 23, 2005. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-896**". Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that with approval of this NDA you have completed the requirements for the study of Emtriva in pediatric subjects from 3 months through 18 years of age. We are deferring submission of your pediatric studies in subjects from birth through 3 months of age until March 30, 2006.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Submission of the results of an ongoing study of the pharmacokinetics, safety, and antiviral activity of emtricitabine in patients 0 (birth) to 3 months of age.

   Final Report Submission: March 30, 2006

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment**".

We remind you of your postmarketing study commitment number 1 in the July 3, 2003 approval letter for NDA 21-500 EMTRIVA® (emtricitabine) 200mg Capsules. This commitment is listed below:

Continue to evaluate and provide a full and complete report on the mechanism of action and skin discoloration observed in patients in emtricitabine clinical trials.

Name of protocol: Protocol GS-01-934 "A Phase 3, Randomized, Open-Label, Multicenter Study of the Treatment of Antiretroviral-Naïve, HIV-1-Infected Subjects Comparing Tenofovir Disoproxil Fumarate and Emtricitabine in Combination with Efavirenz Versus Comitia (lamivudine/zidovudine) and Efavirenz".
Protocol Submission: February 20, 2004 to IND 53,791/SN-701; as amended October 20, 2004 as SN-732
Study Start: July 23, 2003
Final Report Submission: January 2, 2006

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this to the Division of Antiviral Products and two copies of both the promotional materials and the package insert directly 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

Please submit one market package of the drug product when it is available.

We have completed validation of the regulatory methods.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We remind you to send any submissions to the IND or NDA to the following address.

Food and Drug Administration
Center for Drug Evaluation Research
Division of Antiviral Products
5901-B Ammendale Road
Beltsville, MD 20705-1266.

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 Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Approved labeling (Package Insert, Patient Package Insert, Carton, and Container)

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
9/28/2005 09:31:38 AM
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