



NDA 21-896/S-001
NDA 21-500/S-007

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 supplemental new drug application (NDA) 21-896 dated and received June 29, 2006, 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 July 28, 2006, August 28, 2006, and September 11, 2006, September 14, 2006, November 28, 2006, and December 20, 2006, received July 31, 2006, August 30, 2006, September 12, 2006, September 15, 2006, November 29, 2006, and December 21, 2006.

Also, please refer to your supplemental NDA 21-500 dated September 19, 2006, and received September 20, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMTRIVA[®] (emtricitabine) 200 mg Capsules.

These NDA supplements support the inclusion of pharmacokinetic data for children from birth to three months of age in the label. They also revise the labeling to conform to the most recent supplemental labeling for TRUVADA[®] (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) Tablets (NDA 21-752/S-005) approved March 8, 2006.

We have completed our review of these applications, as amended. They are 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 the patient package insert) submitted December 22, 2006. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

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/S-001 and NDA 21-500/S-007**". Approval of these submissions 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 you have fulfilled the pediatric study requirement for these applications as of the date of this letter.

We also remind you of the postmarketing commitments in the approval letter for NDA 21-500 EMTRIVA[®] (emtricitabine) 200 mg Capsules dated July 2, 2003, and the approval letter for NDA 21-896 EMTRIVA[®] (emtricitabine) Oral Solution dated September 28, 2005.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division 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

If you issue a letter communicating important information about these drug products (*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 Products
Office of Antimicrobial Products
Center of Drug Evaluation and Research

Enclosure: Final Labeling (Package Insert and Patient Package Insert)

**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
12/22/2006 03:03:48 PM
NDA 21-896, 21-500