DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-937/S-006 **CBE-30/CBE-0 SUPPLEMENT**

Gilead Sciences, Inc.
ATTN: Pamela Danagher, MSc
Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Danagher:

Please refer to your supplemental new drug application dated April 4, 2007, and received April 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ATRIPLA (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

1. Addition of bepridil and pimozide as agents contraindicated for use with SUSTIVA (efavirenz).

2. Addition of pharmacokinetic information for atorvastatin, diltiazem, itraconzole, pravastatin, and simvastatin in Table 1: Drug Interactions: Changes in Pharmacokinetic Parameters for Efavirenz in the Presence of the Coadministered Drug.

3. Revision to the pharmacokinetic information for rifampin in Table 1: Drug Interactions: Changes in Pharmacokinetic Parameters for Efavirenz in the Presence of the Coadministered Drug.

4. Although a dosing recommendation was added to the SUSTIVA PI for efavirenz dose reduction for coadministration with voriconazole, please note that this change is not incorporated into the ATRIPLA PI because the recommendation for reduction in the efavirenz dose cannot be achieved with the fixed-dose combination product.

5. Updating the information in the Antiretroviral Pregnancy Registry information.

6. In addition to the changes made to incorporate changes to the SUSTIVA PI as described above, minor editorial changes are included with this revised ATRIPLA PI. The purpose of these minor editorial changes are to harmonize the format and usage of the trademark and brand name information within the Atripla PI to conform with the approach for labeling for other Gilead products.

   Specifically, a registered trademark is now utilized only for products of Gilead Sciences, Inc. or Bristol-Myers Squibb. In addition, a change has been made in the use of capital versus lower-case letters for product brand names, where relevant. These minor editorial changes are introduced at this time for convenience.

7. Revision of copyright information to reflect the date of approval.

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.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling. 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 21-937**."

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

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 S. Holloman, BS Pharm, JD, Regulatory Health Project Manager, at (301) 796-0731.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, MD
Director
Division of Antiviral Products (DAVP)
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Final Agreed-Upon Labeling

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
2/15/2008 02:12:46 PM
NDA 21-937