DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-449/S-009

Gilead Sciences, Inc
ATTN: Nikki McMillan
Manager, Regulatory Affairs
4611 University Drive
4 University Place
Durham, NC 27707

Dear Ms. McMillan:

Please refer to your supplemental new drug application dated March 20, 2006, received March 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HEPSERA (adefovir dipivoxil, ADV) 10 mg Tablets.

We acknowledge receipt of your submissions dated June 2, 2006, and September 13, 2006, and received June 5, 2006 and September 14, 2006.

This supplemental new drug application provides for the use of HEPSERA (adefovir dipivoxil) 10 mg Tablets for the treatment of chronic hepatitis B virus infection.

This supplemental new drug application provides for revisions to the package insert to add information to the CLINICAL PHARMACOLOGY, Pharmacokinetics, Drug Interactions section based on data from three final pharmacokinetic study reports for Studies GS-02-531, GS-US-103-106, and GS-US-103-535. Specifically, tacrolimus or cyclosporine, when coadministered with HEPSERA, were evaluated in subjects following liver transplantations. Also, enteric-coated didanosine, and pegylated interferon α-2a were added to the list of drugs that have been evaluated in healthy volunteers in combination with HEPSERA. Finally, the trademark information in both the PI and PPI was updated as of the date of approval of this supplement.

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 text for the patient package insert) submitted September 12, 2006.

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 21-449/S-009**." Approval of this submission by FDA is not required before the labeling is used.

We also remind you of your postmarketing study commitments from the NDA approval letter dated September 20, 2002.

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 20857

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 Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and

Enclosure: Final Agreed-Upon Labeling (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

9/20/2006 04:33:19 PM