DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-449/S-011

Gilead Sciences, Inc
ATTN: William C. Kershaw, PhD, DABT
Associate Director, Regulatory Affairs
4611 University Drive
4 University Place
Durham, NC 27707

Dear Dr. Kershaw:

Please refer to your supplemental new drug application dated June 22, 2007, received June 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HEPSERA® (adefovir dipivoxil) 10 mg Tablets for the treatment of chronic hepatitis B virus infection.

We acknowledge receipt of your submissions dated July 17, 2007, July 19, 2007, August 17, 2007, September 12, 2007, October 15, October 16, October 19, 2007, October 23, 2007, October 26, 2007, November 5, 2007, November 16, 2007, and November 29, 2007.

This supplemental new drug application provides for the use of HEPSERA® (adefovir dipivoxil) for the treatment of chronic hepatitis B in pediatric patients (ages 12 to 17 years).

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 submitted labeling dated December 19, 2007. 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 21-449**."

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 ages 2 to 17 years of age as of the date of this letter. We are waiving the pediatric study requirement for ages birth to 2 years for this application.

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 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 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
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Final Agreed-upon 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
12/19/2007 04:55:04 PM
NDA 21-449