DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-449 SLR 016

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Laura Bacot
Associate Manager, Regulatory Affairs
4611 University Drive
4 University Place
Durham, NC 27707

Dear Ms. Bacot:

Please refer to your supplemental new drug application dated April 17, 2009, received April 20, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hepsera® (adefovir dipivoxil) 10 mg tablets.

We acknowledge receipt of your submission dated August 28, 2009.

This Prior Approval supplemental new drug application provides for the following revisions to the package insert (PI):

- To add information under Warnings and Precautions and the Drug Interactions sections regarding the co-administration of Hepsera with other products containing tenofovir disoproxil fumarate;
- To add a recommendation to calculate creatinine clearance before initiating therapy; and
- To add pancreatitis to the postmarketing experience section.

In addition, the following revisions were made to the patient package insert (PPI):

- To add information regarding co-administration of Hepsera with other products containing tenofovir disoproxil fumarate; and
- To add side effects associated with Hepsera to the “What are the possible side effects of Hepsera?” section.

We have completed our review of this application as amended. The application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. that is identical to the package insert and patient package insert enclosed. 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 SLR 016."

LABELING

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

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
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 Sherly Abraham, R.Ph., Regulatory Project Manager, at (301)796-3198.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures:
Package Insert
Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21449	SUPPL-16	GILEAD SCIENCES INC	HEPSERA (ADEFOVIR DIPIVOXIL) 10MG TABS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VICTORIA L Tyson
10/16/2009

KENDALL A MARCUS
10/16/2009