**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-003/S-010
NDA 21-004/S-010

GlaxoSmithKline
Attention: Dr. Susan L. Watts, Associate Director
Antiviral/Antibacterial, US Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Watts:

Please refer to your supplemental new drug applications dated April 4, 2007, received April 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EPIVIR-HBV® (lamivudine) tablets and EPIVIR-HBV® (lamivudine) oral solution.

Reference is also made to FDA comments dated August 2, 2007, September 13, 2007, September 14, 2007 and September 19, 2007 and your correspondence dated August 21, 2007 and September 13, 2007.

This supplemental new drug application provides for:

- ***Revisions to the US package insert to revise the antiviral activity, resistance, and cross resistance sections under the Microbiology heading of the Epivir-HBV label as well as to incorporate data from published studies and research reports (NUC20904, RM2005/0059/00, and other studies).***

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.

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
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 Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

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

Enclosure (Approved Labeling)

---

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

---

/s/
---
Jeffrey Murray
9/26/2007 04:07:24 PM