DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-596/S-025
NDA 20-564/S-024

GlaxoSmithKline
Attention: Susan L. Watts, Ph.D.
Associate Director
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Watts:

Please refer to your supplemental new drug applications dated January 9, 2006, received January 10, 2006, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act for Epivir® (lamivudine) Tablets and Epivir® (lamivudine) Oral Solution.

We acknowledge receipt of your submissions dated January 9, 2006.

These "Changes Being Effected" supplemental new drug applications provide for:

> To update CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the prescribing information to include class labeling regarding drug interactions with coadministration of ribavirin or interferon with EPIVIR®. Additionally, updates have been made to the MICROBIOLOGY, CLINICAL PHARMACOLOGY and PRECAUTIONS section as requested in the correspondence dated September 29, 2005.

We completed our review of these applications, as amended on March 31, 2006. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 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
6/13/2006 04:22:15 PM