



DEPARTMENT OF HEALTH & HUMAN

Public Health Service

Food and Drug Administration

Rockville, MD 20857

NDA 20-596/S-027

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 application dated October 13, 2006, received October 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EPIVIR® (lamivudine) oral solution.

This “Changes Being Effectuated” supplemental new drug application provides for:

- ***Changes to the MICROBIOLOGY section of the US package insert.***

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
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 Paras M. Patel, 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/

Debra Birnkrant
10/25/2006 09:35:41 AM
NDA 20-596