



NDA 21-003/S-005

NDA 21-004/S-006

GlaxoSmithKline
ATTN: Susan Watts, Ph.D
P.O. Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Dear Dr. Watts:

Please refer to your supplemental new drug applications dated March 31, 2004, received April 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EPIVIR-HBV (lamivudine) tablets and oral solution.

These supplemental new drug applications provide for changes under Special Populations: Adult with Impaired Renal Function subsection of CLINICAL PHARMACOLOGY section, Overdosage and Dose Adjustment sections.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling for the package insert submitted October 1, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Vasavi Reddy, RPh, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office Drug Evaluation IV
Food and Drug Administration

Attachment:

FPL

**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
11/22/04 09:12:17 AM