



NDA 20-564 (S-019)  
NDA 20-596(S-020)

GlaxoSmithKline  
Attn: Susan L. Watts, Ph.D.  
P.O. Box 13398  
Five Moore Drive  
Research Triangle Park  
North Carolina 27709-3398

Dear Dr. Watts:

Please refer to your supplemental new drug applications dated September 12, 2003, received September 16, 2003, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epivir<sup>®</sup> (lamivudine) tablets and oral solution.

We acknowledge receipt of your submissions "Changes Being Effected, Labeling" dated September 12, 2003.

These "Changes Being Effected" supplemental new drug applications provide for the following sections: DESCRIPTION, INFORMATION TO PATIENT, DRUG INTERACTIONS, and OVERDOSAGE.

We completed our review of these supplemental new drug applications, they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 12, 2003.

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

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, R.Ph., Regulatory Project Manager, at (301)827-2413.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.,  
Division Director  
Division of Antiviral Drug Products

-----  
**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  
11/13/03 10:07:37 AM