DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-857/S-014

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Dear Dr. Watts:

Please refer to your supplemental new drug application dated April 6, 2004, received April 7, 2004. submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivir® (lamivudine/zidovudine) tablets.

We acknowledge receipt of your submissions "Changes Being Effected, Labeling" dated September 16, 2003.

These "Changes Being Effected" supplemental new drug applications provides for updates to the following sections:

- CLINICAL PHARMACOLOGY: Nursing Mothers subsection
- PRECAUTIONS: Nursing Mothers subsection
- ADVERSE REACTIONS: Observed During Clinical Practice subsection

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 final printed labeling (FPL) submitted on April 6, 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

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
5/17/04 01:12:32 PM