DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-857/SN-018

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 January 9, 2006, received January 10, 2006, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act for Combivir® (lamivudine/zidovudine) Tablets.

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 Combivir®. 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. These applications are 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 enclosed labeling patient package insert submitted April 3, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-857/S-018**." Approval of these submissions by FDA is not required before the labeling is used.

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

6/27/2006 04:54:08 PM