DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-857/S-009
NDA 20-857/S-010

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Antiviral Group-Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC
27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated September 6, 2001 and December 17, 2001, received September 7, 2001 and December 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivir™ (lamivudine/zidovudine) 150mg and 300mg tablets.

We acknowledge receipt of both of your submissions dated March 6, 2002.

Supplemental application 009 provides for updating the label with changes to the WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections. Supplemental application 010 is a CBE, which provides for the addition of oral mucosal pigmentation and gyencomastia to the Observed During Clinical Practice section of the label.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 6, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). In addition, please submit a Microsoft Word version of the label electronically. 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. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-857/S-009 and 010." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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 Christine Lincoln, RN, MS, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

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