DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-564/S-014
NDA 20-596/S-015

GlaxoSmithKline
Attention: Robert Watson
Product Director, Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Watson:

Please refer to your supplemental new drug applications dated June 19, 2000, received June 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Epivir® (lamivudine), 150mg tablets and oral solution.

We acknowledge receipt of your submissions dated August 30, 2000, September 12, 2001, October 12, 2001, October 25, 2001, January 16, 2002, February 15, 2002, March 1, 2002, and August 20, 2002.

These supplemental new drug applications provide for the addition of the results of studies in late pregnancy (i.e. ZDVB1003, NUCB2018, and COL30126/COL10015).

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 products are 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 submitted August 20, 2002.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). In addition, please submit a clean copy MS Word version of the label on diskette to the electronic document room, and as a desk copy. 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, these submissions should be designated "FPL for approved supplement NDA 20-564/S-014, and 20-596/S-015." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Please note that the requirements of 21 CFR 314.55 (or 601.27) that were noted in our letter of June 24, 2002, approving supplements NDA 20-564/S-015 and 20-596/S-016 still apply as stated in that letter.

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, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Acting 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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NDA 20-596, NDA 20-564