CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-564/S-012
20-596/S-013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-564/S-012
NDA 20-596/S-013

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

Dear Ms. Martinson:

Please refer to your supplemental new drug applications dated August 26, 1999, received August 27, 1999, 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:

March 21, 2000 September 12, 2000 January 23, 2001

These supplemental new drug applications provide for the addition of Geriatric Use information and include changes to the **CLINICAL PHARMACOLOGY**, and **PRECAUTIONS**, sections 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 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 (package insert submitted January 23, 2001).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-564/S-011, 20-596/S-012, 20-564/S-012, and 20-596/S-013." In addition, please submit a clean copy MS Word version of the label on diskette as a desk copy. 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 Practitioner" 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,

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

/s/

Debra Birnkrant
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NDA 20-564/S-012, NDA 20-596/S-013