DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-951/S-017

GlaxoSmithKline
Attention: Martha Anne A. Moore, RPh
Product Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated September 19, 2000 and received September 20, 2000 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR® (zidovudine) IV Infusion.

This supplemental new drug application was submitted in response to the Division's comments about needed revisions to the RETROVIR labeling and provides for changes in the following sections of the final printed labeling:

1. Revision of the Nursing Mothers section in the PRECAUTIONS section;
2. Revision of the Antiretroviral Registry sections in the PRECAUTIONS section; and
3. Minor editorial changes throughout the insert.

We have completed the review of this supplemental application, 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, this supplemental application, with the minor changes listed above, is approved effective on the date of this letter.

Approval of this submission by FDA is not required before the labeling is used. However, marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

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 Marsha Holloman, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Printed Labeling Submitted September 19, 2000 by Sponsor

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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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