DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-951/S-018

GlaxoSmithKline, Inc
ATTN: Martha Anne A. Moore, RPh
Director, Antiviral/Antibacterial Regulatory Affairs
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug application dated November 26, 2001, received November 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR® (zidovudine) IV Infusion.

We have completed our review of this supplemental application, 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 application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted November 26, 2001).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-951/S-0018". 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 you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA set forth in 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

Attachment: Agreed-upon Labeling (PI)

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
7/25/03 02:21:34 PM
NDA 19-951