DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-655/S-041
NDA 19-910/S-029
NDA 20-518/S-013

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

Dear Ms. Moore:

Please refer to your supplemental new drug applications (NDAs) dated November 9, 2005, received November 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR (zidovudine) 100 mg Capsules, RETROVIR (zidovudine) 15 mg/5 mL Syrup, and RETROVIR (zidovudine) 300 mg Tablets.

We also refer to your amendment to your supplemental NDAs dated May 8, 2006.

These "Changes Being Effected" supplemental new drug applications provide for the following changes in the package insert:

1. Reorganization and update of the Microbiology section
2. Addition of a new section entitled *Ribavirin* to the CLINICAL PHARMACOLOGY: Pharmacokinetics section
3. Addition of a new section entitled *Immune Reconstitution Syndrome* to the PRECAUTIONS section
4. Addition of a new section entitled *Use with Interferon- and Ribavirin-Based Regimens* in the WARNINGS: Drug Interactions section
5. Correction of minor grammar and spelling errors
6. Correction of the copyright information.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon draft labeling (attached package insert).

The final printed labeling (FPL) must be identical to attached labeling (text for the package insert). Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-655/S-041, NDA 19-910/S-029, NDA 20-518/S-013.**" Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the agreed-upon printed labeling (attached package insert) you propose to use for these products. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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) 796-0731.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved Draft Labeling (Package Insert)

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
5/10/2006 04:50:23 PM
NDA 20-518, 19-655, 19-910