DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-655/S-039
NDA 19-910/S-027
NDA 20-528/S-011

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 April 11, 2003 and received April 14, 2003 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR® (zidovudine) Capsules, RETROVIR® (zidovudine) Syrup, and RETROVIR® (zidovudine) Tablets.

We have completed our review of these applications, as amended. Accordingly, these applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to the RETROVIR® professional package insert:

1. Addition of the word "hypromellose" and deletion of the words "hydroxypropyl methylcellulose".

2. Addition of a subsection entitled "Fat Redistribution" to the PRECAUTIONS section.

3. Addition of a paragraph under the Information for Patients section explaining fat redistribution.

4. Addition of "fat redistribution/accumulation" to the ADVERSE REACTIONS: Observed During Clinical Practice section.

5. Updating the copyright information at the end of the package insert.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) dated April 11, 2003.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "**FPL for approved supplement NDA 19-655/S-039, NDA 19-910/S-027, and NDA 19-518/S-011**". Approval of these submissions by FDA is not required before the labeling is used.

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 (21 CFR 314.80 and 314.81).

If you have any questions, call Marsha S. 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: Final Printed 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/

Jeffrey Murray
10/15/03 10:41:23 AM