DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-655/S-038
NDA 19-910/S-026
NDA 20-518/S-010

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 January 14, 2001 and received January 15, 2002 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR® (zidovudine) Capsules, RETROVIR® (zidovudine) Syrup, and RETROVIR® (zidovudine) Tablets.

These supplemental new drug applications were submitted to revise the RETROVIR labeling by adding "pure red cell aplasia" to the ADVERSE EVENTS, Observed During Clinical Practice, *Hemic and Lymphatic* section of the final printed labeling: Also, the copyright date was revised.

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, with the minor changes listed above, are approved effective on the date of this letter.

Please submit the final printed labeling (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-038, NDA 19-910/S-026, and NDA 19-518/S-010." Approval of these submissions by FDA is not required before the labeling is used.

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,

Jeffrey S. Murray, MD, MPH
Deputy Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Printed Labeling Submitted January 14, 2002 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/

Jeffrey Murray
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