DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-655/S-037
NDA 19-910/S-025
NDA 20-518/S-009

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 June 7, 2001 and August 7, 2001 and received July 8, 2001 and August 8, 2001 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 in response to the Division's comments about needed revisions to the RETROVIR labeling and provide for changes in the ADVERSE REACTIONS, Observed During Clinical Practice section of the final printed labeling (see attached.):

1. Endocrine: gynecomastia; and
2. Gastrointestinal: oral mucosal pigmentation.

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, attached labeling text. Accordingly, these supplemental applications, with the minor changes listed above, are approved effective on the date of this letter.

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 S. Holloman, BS Pharm, JD, Regulatory 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 June 7, 2001 and August 7, 2001 by Sponsor

---

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
2/21/02 09:28:09 AM
NDA 19-655, 19-910, 20-518