DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-910/ S-033
NDA 19-655/S-046
NDA 20-518/S-016

NDA APPROVAL

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Infectious Diseases, US Regulatory Affairs
P.O. Box 13398
Five Moore Drive,
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications (NDA) dated March 21, 2008, and September 17, 2008, received March 21, 2008 and September 17, 2008 , submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RETROVIR (zidovudine) syrup, capsules and tablets.

We acknowledge receipt of your submissions dated:

June 13, 2008	July 17, 2008	August 1, 2008
August 15, 2008	August 27, 2008	September 11, 2008

These supplemental new drug applications provide for an alternative dosing regimen, twice daily dosing, of RETROVIR (zidovudine) syrup, capsules and tablets in pediatric patients 6 weeks to < 18 years of age for the treatment of HIV-1 infection in combination with other antiretroviral agents.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved supplement NDA 19-910/S-033, NDA 19-655/S-046 and NDA 20-518/S-016.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for neonates from birth to < 1 month of age because necessary studies are impossible or highly impracticable.

Your deferred pediatric study, required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act, is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1. **Deferred pediatric study under PREA for the treatment of HIV-1 infection in pediatric patients ages 1 month to < 6 weeks of age. Please assess zidovudine pharmacokinetic data in neonates and use pharmacokinetic modeling and simulation data to propose dosing recommendations for HIV-1 infected children between 1 month and < 6 weeks of age.**

   Final Report Submission: March 31, 2009

Submit final study reports to these NDAs. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment**".

We note that you have fulfilled the pediatric study requirement for ages 6 weeks to < 18 years of age for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package inserts directly to:

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
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 Jaewon Hong, PharmD, Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert and Patient 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
9/19/2008 02:20:33 PM