DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-857/S-023

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Five Moore Drive, Bldg 5.5218
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug application dated June 13, 2008, received June 13, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, for Scored COMBIVIR® (lamivudine and zidovudine) tablets 150 mg/300 mg.

We also acknowledge receipt of your submissions dated September 25, 2008, October 15, 2008, and December, 2, 2008, December 18, 2008, and December 19, 2008.

This supplemental new drug application provides for the use of scored COMBIVIR® (lamivudine and zidovudine) tablets 150 mg/300 mg for the treatment of HIV-1 infection, in combination with other antiretroviral agents, in pediatric patients weighing greater than or equal to 30 kg.

We completed our review of this application, as amended. This application is 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, immediate container and carton label) submitted on December 18, 2008.

Within 14 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/submitted labeling dated December 18, 2008. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, 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
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
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 Amalia Himaya, Regulatory Project Manager, at (301) 796-3391.

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, Immediate Container, and Carton Label

---

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
2/2/2009 03:42:27 PM