DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-205/S-014

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Antiviral/Antibacterial US Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug application dated January 10, 2006, received January 11, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trizivir® (abacavir sulfate/lamivudine/zidovudine) tablets.

We also acknowledge receipt of your submission dated April 26, 2006 and received April 27, 2006 amending the January 20, 2006 submission.

This "Changes Being Effected" supplemental new drug application provides for updates to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the Trizivir® Tablets prescribing information to include class labeling regarding drug interactions with coadministration of ribavirin or interferon with Trizivir® also to modify the list of the most common adverse reactions and to add information regarding immune reconstitution to the medication guide.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, please contact Tanima Sinha, M.S., Regulatory Project Manager, at (301) 796-0812.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant
Director
Division of Antiviral Products
Office of Antimicrobial Products

Enclosure: Approved Final 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
8/11/2006 03:37:34 PM