

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205/S-006

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

Dear Ms. Moore:

Please refer to your supplemental new drug application (NDA 21-205/S-006) dated July 17, 2002, received July 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trizivir® (abacavir sulfate, lamivudine, and zidovudine) Tablets.

This "Changes Being Effected" supplemental new drug application provides for updated Trizivir® (abacavir sulfate, lamivudine, and zidovudine) Tablets labeling to include information about fat redistribution in both the package insert and Medication Guide.

We have completed the review of this supplemental application 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 submitted final printed labeling (package insert and Medication Guide submitted on July 17, 2002). Accordingly, this supplemental application is 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, please call Virginia Yoerg, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely yours,

{See appended electronic signature page}

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

Attachment: FPL dated July 17, 2002

**APPEARS THIS WAY
ON ORIGINAL**