CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205/S-003, S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

GlaxoWellcome Inc.
Attention: Martha Anne A. Moore, R.Ph.
Antiviral Group-Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated October 17, 2001 and February 7, 2002, received October 18, 2001 and February 8, 2002, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trizivir® (abacavir sulfate, lamivudine, and zidovudine) tablets.

These Labeling Supplements-Changes Being Effected update the Trizivir® tablets labeling to reflect recently approved changes made to the Ziagen (abacavir sulfate), Epivir (lamivudine), and Retrovir (zidovudine) labeling. Revised sections include **CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS**, and **ANIMAL TOXICOLOGY**.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling. Accordingly, these supplemental applications 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 Virginia L. Yoerg, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely,

{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

APPEARS THIS WAY
ON ORIGINAL