



NDA 20-977/S-010
NDA 20-978/S-012

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 applications dated November 25, 2002, received November 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ziagen® (abacavir sulfate) Tablets and Oral Solution.

We acknowledge receipt of your submissions dated May 20, 2003 and June 17, 2003.

These supplemental new drug applications provide for revisions to the Clinical Pharmacology and Dosage and Administration sections for Ziagen® (abacavir sulfate) Tablets and Oral Solution package insert regarding its use in patients with hepatic impairment. We have completed the review of these supplemental applications, as amended, 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 submitted June 17, 2003.) 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 in 21 CFR 314.80 and 314.81.

If you have any questions, please call Tanima Sinha, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

Attachment: FPL dated June 17, 2003

**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
7/17/03 08:36:10 AM