



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 applications (NDA 20-977/S-008 and NDA 20-978/S-00010) dated July 15, 2002, received July 16, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ziagen® (abacavir sulfate) Tablets and Oral Solution.

These "Changes Being Effected" supplemental new drug applications provide for updated Ziagen (abacavir sulfate) Tablets and Oral Solution labeling to include information about fat redistribution in both the package insert and Medication Guide.

We have completed the review of these supplemental applications 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 15, 2002). 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, please call Virginia Yoerg, Regulatory 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 15, 2002

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Debra Birnkrant
8/14/02 10:28:01 AM
NDA 20-978 SLR 010, NDA 20-977 SLR 008