DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-977/S-005
NDA 20-978/S-006

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

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated June 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ziagen (abacavir sulfate) Tablets and Ziagen (abacavir sulfate) Oral Solution.

We acknowledge receipt of your submissions dated November 20, 2001 and November 29, 2001.

The supplemental new drug application provides for the inclusion of carcinogenicity study results in the package insert for Ziagen products. Included in this supplemental new drug application are the final carcinogenicity study reports. These changes are noted in the **PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility** section.

We have completed the review of the supplemental application, 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 agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed final draft labeling dated November 29, 2001. Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount 10 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-977/S-005, 20-978/S-006." Approval of these submissions by FDA is not required before the labeling is used.

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 Karen A. Young, Regulatory Project Manager, at (301) 827-2376.

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

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
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NDA 20-977, SLR 005, NDA 20-978, SLR 006