DEPARTMENT OF HEALTH & HUMAN Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-977/SLR-013
NDA 20-978/SLR-015

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

Dear Ms. Moore:

Please refer to your supplemental new drug applications NDA 20-977/SLR-013 and NDA 20-978/SLR-015 dated May 14, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZIAGEN® (abacavir sulfate) Tablets and Oral Solution.

We also acknowledge receipt of your submissions dated: 22 June 2004, 29 June 2004, 6 July 2004, 8 July 2004 (2) and 14 July 2004.

We have completed our review of these applications, as amended. These labeling supplements updated the text of Hypersensitivity Reactions (HSR) in the professional labeling, Medication Guide, and Warning Card. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the Package Insert, Medication Guide and Warning Card. These revisions are terms of the approval of these applications. Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 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/SLR-013, and NDA 20-978/SLR-015." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D.
Deputy Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Attachment: Approved Draft Labeling

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
7/26/04 04:08:03 PM