DEPARTMENT OF HEALTH & HUMAN

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-977/SLR16
NDA 20-978/SLR19

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 and 20-978 dated October 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ziagen® (abacavir sulfate) tablets and oral solution.

These supplements (CBE) provide updates to the MICROBIOLOGY section of the full prescribing information for Ziagen® (abacavir sulfate) tablets and oral solution.

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

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Health Project Manager, at (301) 796-0812.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products

Enclosure: Final Approved Label

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
5/7/2007 11:21:13 AM
NDA 20-978, 20-977