CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-977 / S-014
20-978 / S-016

Trade Name: Ziagen

Generic Name: (abacavir sulfate)

Sponsor: GlaxoSmithKline

Approval Date: August 11, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-977/S-014
NDA 20-978/S-016

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 January 10, 2006, received January 11, 2006, 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 April 26, 2006 received April 27, 2006 amending the January 20, 2006 submission.

These supplements (CBE) provide updates to the CLINICAL PHARMACOLOGY and PRECAUTION sections as requested by the Division. Also included are updates to the MICROBIOLOGY section to incorporate the updated lamivudine and zidovudine information approved in the Trizivir® tablets prescribing information approved on May 13, 2005. The information regarding Study CNA2005 has also been updated to agree with the approved Trizivir® prescribing information. The Medication Guide has been revised to advise patients to tell their doctor before they take Ziagen® if they have liver problems. Also added is information regarding immune reconstitution to the Medication Guide.

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
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 Project Manager, at (301) 796-0812.