DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-014 **CBE LABELING SUPPLEMENT**

SmithKlineBeecham d/b GlaxoSmithKline
ATTN: Susan L. Watts, PhD
Director, US Regulatory Affairs
PO Box 13398
R&D Room 5.5351.5C
5 Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Watts:

Please refer to your supplemental new drug application dated and received April 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LEXIVA® (fosamprenavir calcium, FPV) Oral Tablets.

We acknowledge receipt of your submissions dated June 28, 2007, and November 7, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of labeling for LEXIVA to reflect a drug-drug interaction with phenytoin based on the results of Study APV107484 , entitled "*A Phase I, Randomized, Open-Label, Four-Arm, Two-Period, Two 2x2, Crossover, Drug-Interaction Study to Assess Steady-State Plasma Amprenavir and Phenytoin Pharmacokinetics following Administration of Fosamprenavir 700 mg BID + Ritonavir 100 mg BID + Phenytoin 300 mg Daily, Fosamprenavir 700 mg BID + Ritonavir 100 mg BID, and Phenytoin 300 mg Daily in Health Adult Subjects.*"

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved NDA 21-548**."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert.)

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Marsha S. Holloman, BS Pharm, JD, Regulatory Health Project Manager, at (301) 796-0731.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, MD
Director
Division of Antiviral Products (DAVP)
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Final Agreed-upon Labeling

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
12/13/2007 02:49:08 PM
NDA 21-548