DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-016

GlaxoSmithKline
Attn: Susan L. Watts, Ph.D.
Director, US Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Watts:

Please refer to your supplemental new drug application dated June 7, 2007, received June 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva (fosamprenavir calcium) Tablets.

We acknowledge receipt of your amended submission dated December 18, 2007.

This supplemental new drug application includes:

- Proposed revisions to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of labeling to include the results of Study COL102577 *(A Phase I, Open-Label, 2-Period, Single-Sequence, Drug Interaction Study to Assess Steady-State Plasma Methadone Enantiomer Pharmacokinetics Following Co-Administration of Methadone QD with Fosamprenavir 700mg BID + RTV 100mg BID in Opiate-Dependent, HIV Seronegative, Adult Subjects).* These changes include revising the methadone clinical comment in Table 6 under DRUG INTERACTIONS and adding methadone to Tables 10 & 12 under CLINICAL PHARMACOLOGY.

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

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

In addition, within 14 days of the date of this letter, amend any pending applications for Lexiva (NDA 21-548/S-017 and NDA 22-116/S-001) with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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 Elizabeth Thompson, MS, Regulatory Project Manager, at (301) 796-0824.

Sincerely,

{See appended electronic signature page}
Debra Birnkrant, M.D.
Director
Division of Antiviral Products
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/

Jeffrey Murray
2/20/2008 02:51:34 PM