DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-019
NDA 22-116/S-003

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 applications dated March 26, 2008, received March 26, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva (fosamprenavir calcium) Tablets and Oral Suspension.

These Changes Being Effected supplemental new drug applications provide for the following revisions:

- **Postmarketing Experience**, Skin and Subcutaneous Tissue Disorders: Angioedema was added under Section 6.2 of the Full Prescribing Information.
- Corresponding information regarding angioedema was added to the Patient Information under **What are the possible side effects of LEXIVA?**

We completed our review of these applications, and they are 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 submitted labeling (package insert and patient package insert submitted March 26, 2008).

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 (clean copy of approved 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
4/30/2008 11:20:41 AM
NDA 22-116, 21-548