



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-017

NDA 22-116/S-001

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 August 3, 2007, received August 3, 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 February 21, 2008.

This supplemental new drug application includes:

- Correction to age range in package insert under section 2.2 Therapy-Naïve Pediatric Patients
- Correction to storage statement
- Minor editorial changes

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).

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
3/5/2008 03:22:48 PM
NDA 22-116, 21-548