DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20903

NDA 21-548/SLR-007

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Benson:

Please refer to your new drug application (NDA) dated September 30, 2005, received October 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva® (fosamprenavir calcium) tablets.

We acknowledge receipt of your Special Supplement "Changes Being Effected, Labeling" dated September 30, 2005 submitted in response to a letter from the Division dated April 11, 2005.

This "Changes Being effected" supplemental new drug application updates the WARNINGS and PRECAUTIONS section of the label to include information regarding immune reconstitution syndrome and drug-drug interactions with fluticasone proprionate and trazodone. The wording of Immune Reconstitution section of PRECAUTIONS has been updated to comply with the class labeling for antiretroviral agents for the treatment of HIV infection.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (FPL) submitted with the supplement.

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 Kenny Shade, Regulatory Project Manager, at (301)796-0807 or (301)796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Office of Antiviral Products
Division of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:

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

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