



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-548/S-005

GlaxoSmithKline  
Attention: Eric B. Benson  
Senior Director, US Regulatory Affairs  
P.O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709-3398

Dear Mr. Benson:

Please refer to your supplemental new drug application dated May 13, 2005, received May 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva® (fosamprenavir calcium) tablets.

This supplemental new drug application provides for revisions to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the labeling (package insert) for Lexiva based on the results of Study APV10031.

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 labeling submitted May 13, 2005.

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-548/SN-005.**" Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant

Director

Division of Antiviral Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research

Enclosure:

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jeffrey Murray

11/10/2005 08:11:19 AM