DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-002

GlaxoSmithKline
Attention: Eric B. Benson
Senior Director Antiviral/Antibacterial Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Benson:

Please refer to your supplemental new drug application dated August 11, 2004, received August 11, 2004, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Lexiva® (Fosamprenavir calcium) tablets 700 mg.

This supplemental new drug application provides for revisions to the Precautions, Overdosage, and Dosage and Administration sections of Lexiva product labeling.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-548/S-002." 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) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center of Drug Evaluation and Research

Enclosure: approved draft 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
11/29/04 04:41:38 PM
NDA 21-548