



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-011

GlaxoSmithKline
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 August 1, 2006, received August 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva® (fosamprenavir calcium) tablets.

We acknowledge receipt of your submission dated October 6, 2006.

This supplemental new drug application provides revisions to the CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS and PATIENT INFORMATION section of labeling for Lexiva regarding the interaction of fosamprenavir with oral contraceptives based on the results of Study APV10020.

We completed our review of this supplemental new drug 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 enclosed labeling.

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/S-011.**" 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
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 Kenny Shade, Regulatory Project Manager, at (301) 796-0807.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

**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
11/14/2006 03:33:52 PM
NDA 21-548