



NDA 21-548/S-004

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

Dear Mr. Benson:

Please refer to your supplemental new drug application dated December 10, 2004, received December 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexiva® (fosamprenavir calcium) tablets.

This supplemental new drug application provides a final study report of Study APV10014 “A Phase I, Open Label, Single Arm, Three Period, Drug-Drug Interaction Study to Assess the Steady-State Plasma Amprenavir and Nevirapine Pharmacokinetics Following Administration of GW433908 1400 mg BID + Nevirapine 200 mg BID for 14 days and GW433908 700 mg BID + Nevirapine 200 mg BID + Ritonavir 100 mg BID for 14 Days in HIV-1 Infected Subjects” in order to fulfill a post-marketing study commitment and propose revisions to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of labeling for Lexiva based on the results of study APV10014.

We completed our review of this supplemental new drug application. 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 for the package insert submitted on June 10, 2005.

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/SN004.**" 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

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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) 827-2361 or (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office Drug Evaluation IV
Food and Drug Administration

Enclosure: Approved Draft Labeling (package insert)

**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
6/13/05 04:13:33 PM