DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-548/S-009

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 February 7, 2006, received February 8, 2006, submitted under section 505(b) of the of the Federal Food, Drug, and Cosmetic Act for Lexiva® (fosamprenavir calcium) tablets.

We acknowledge reference to Investigational New Drug Application (IND) 58,627 for fosamprenavir calcium and your February 18, 2005 submission to that IND (Serial No. 0329) of Protocol APV10026 for a study of the pharmacokinetic interaction of Lexiva and ketoconazole.

This supplemental new drug application provides for revisions to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of labeling for Lexiva to reflect the final results of Study APV10026.

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 approval supplement NDA 21-548/S-009."** 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 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

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
8/7/2006 08:38:08 AM
NDA 21-548