DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-363/S-010
NDA 20-363/S-014
NDA 20-363/S-016

SmithKline Beecham Pharmaceuticals
Attention: Edward M. Yuhas, Ph.D.
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

JUN 12 1998

Dear Dr. Yuhas:

Please refer to your June 6, 1996, June 13, 1997, and January 14, 1998, supplemental New Drug Applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Famvir (famciclovir) 125mg, 250mg, and 500mg Tablets.

We acknowledge receipt of your submissions dated:

June 25, 1997	October 17, 1997	April 14, 1998
July 7, 1997	March 5, 1998	
September 26, 1997	March 10, 1998	

The June 13, 1997, supplemental drug application provides for the treatment of recurrent mucocutaneous herpes simplex infections in HIV-infected patients.

The June 13, 1997, supplemental drug application (S-014) supersedes the June 6, 1996 (S-010), and January 14, 1998 (S-016) applications.

We have completed the review of these applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the June 12, 1998, draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the June 12, 1998, draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL and one copy on diskette as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-363/S-010/S-014, and S-016. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitment specified in the June 5, 1998, submission. In this submission you indicted the following:

Under section 736(a)(1)(B)(ii) of the Prescription Drug User Fee Act of 1992, this letter triggers the remaining 50% of the fee assessed for the June 13, 1997, application. You will receive an invoice for the amount due within the next month. Payment will be due within 30 days of the date of the invoice.
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, please contact Melissa M. Truffa, R.Ph., Regulatory Health Manager, at (301) 827-2335.

Sincerely yours,

Heidi M. Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research