DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-603/S-019

Glaxo Wellcome Inc.
Attention: Robert S. Watson
5 Moore Drive
Research Triangle Park, NC 27709

JUN 2 1998

Dear Mr. Watson:

Please refer to your May 30, 1997, supplemental New Drug Application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax®, (acyclovir sodium) for Injection 500 mg and 1000mg vials.

We acknowledge receipt of your submissions dated May 15, and May 29, 1998.

The User Fee goal date for this application is June 2, 1998.

This supplemental drug application provides for the treatment of herpes simplex virus infections in neonatal patients.

We have completed the review of this supplemental application 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 2, 1998, draft labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 2, 1998. 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 supplemental NDA 18-603/S-019. 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.

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 this 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.

Should 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 Anti-Viral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research