ANDA 74-930

MAY 13 1998

Fujisawa USA, Inc.
Attention: Laurence R. Myerson, Ph.D.
3 Parkway North, 3rd Floor
Deerfield, IL 60015-2548

Dear Sir:

This is in reference to your abbreviated new drug application dated July 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Acyclovir Sodium Injection, 50 mg (base)/mL, in 10 mL (500 mg) and 20 mL (1 g) vials.

Reference is also made to your amendments dated May 9, July 18, September 5, October 2, October 31, and December 22, 1997; January 13, January 28, and correspondence dated March 2, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined that your Acyclovir Sodium Injection 50 mg (base)/mL can be expected to have the same therapeutic effect as that of the reference listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ [redacted] 5/13/98

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research