CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 74976

APPROVAL LETTER

ANDA 74-976

APR 13 1998

Lipha Pharmaceuticals, Inc.
U.S. Agent for: Genpharm, Inc.
Attention: Anita Goodman, M.D.
9 West 57th Street, Suite 3825
New York, NY 10019-2701

Dear Madam:

This is in reference to your abbreviated new drug application dated September 27, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Acyclovir Tablets, 400 mg and 800 mg.

Reference is also made to your amendments dated January 16, January 22, February 5, June 2, September 8, and December 12, 1997; and January 7, February 20 and April 9, 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 your Acyclovir Tablets, 400 mg and 800 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zovirax® Tablets, 400 mg and 800 mg, respectively, of Glaxo Wellcome Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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 and 314.98. 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.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies which may be identified.

Sincerely yours,

for 4-13-88

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