

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**40278**

**APPROVAL LETTER**

SEP 30 1998

ANDAs 40-278 (50 mL and 100 mL vials), Pharmacy Bulk Package  
40-279 (10 mL and 20 mL vials)

American Pharmaceutical Partners, Inc.  
Attention: Lincy Michael  
2045 North Cornell Avenue  
Melrose Park, IL 60160

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Dear Madam:

This is in reference to your abbreviated new drug applications dated October 3, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Fluorouracil Injection USP, 50 mg/mL.

Reference is also made to your amendments dated May 13 and July 16, 1998.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Fluorouracil Injection, 50 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Fluorouracil Injection by Hoffman LaRoche Inc.).

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

Post-marketing reporting requirements for these abbreviated applications 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 these drugs.

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,

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and Communications (HFD-40). 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-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

*ISF*

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

*Sporn*  
9-29-88