APPLICATION NUMBER:
40279

APPROVAL LETTER
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: Linsey Michael
2045 North Cornell Avenue
Melrose Park, IL 60160

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

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,
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,

[Signature]

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