

ANDA 40-291

March 24, 1999

Bigmar, Inc.  
Attention: Peter Stoelzle  
9711 Sportsman Club Road  
Johnstown, OH 43031

Dear Sir:

This is in reference to your abbreviated new drug application dated December 31, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Fluorouracil Injection USP, 50 mg/mL, packaged in 250 mg/5 mL and 500 mg/10 mL single-dose vials.

Reference is also made to your amendments dated February 6, May 19, May 29, August 26, October 2, October 15, and November 30, 1998; and February 1, February 4, February 25, February 26, March 10, and March 22, 1999.

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 Fluorouracil Injection USP, 50 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Fluorouracil Injection, 50 mg/mL, of Hoffmann La Roche, Inc.).

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

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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,

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