ANDA 40-266

February 26, 1999

Bigmar, Inc.
Attention: Peter Stoelzle
9711 Sportsman Club Road
Johnstown, Ohio 43031-9141

Dear Sir:

This is in reference to your abbreviated new drug application dated July 31, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Methotrexate for Injection USP, 1 g/vial, (preservative-free).

Reference is also made to your amendments dated February 9, February 19, May 29, June 11, September 18, October 28, November 20, and November 25, 1998; and January 19, and January 27, 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 Methotrexate for Injection USP, 1 g/vial, (preservative-free) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Methotrexate Sodium for Injection USP, 1 g (base)/vial, (preservative-free) of Lederle Laboratories.

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-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