CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40263

APPROVAL LETTER

ANDA 40-263

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 28, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Methotrexate Injection USP, 25 mg/mL, (Preserved) packaged in vials containing 50 mg and 250 mg.

Reference is also made to your amendments dated February 9, February 16, May 29, June 11, September 5, September 25, October 29, November 20, and November 30, 1998; and January 8, January 21, 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 Injection USP, 25 mg/mL, (preserved) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Methotrexate Sodium Injection, 25 mg (base)/mL (preserved) 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,

/S/ 2/26/99

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

cc: ANDA 40-263
Division File
FIELD COPY
HFD-610/JPhillips
HFD-92
HFD-210/B.Poole
HFD-330/
HFD-205/

APPROVAL