DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-770

Food and Drug Administration
Rockville MD 20857

APR 23 2004

Bedford Laboratories
Attention: Molly Rapp
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 23, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Terbutaline Sulfate Injection USP, 1 mg/mL, packaged in 1 mL single-dose vials.

Reference is also made to your two amendments dated November 25, 2003; and to your amendments dated December 19, 2003; and January 30, March 12, and March 18, 2004.

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 Terbutaline Sulfate Injection USP, 1 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Brethine® Injection, 1 mg/mL, of aaiPharma LLC).

Under Section 506A of the Act, 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 final printed

labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 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 FDA 2253 at the time of their initial use.

You have been requested to provide information after the drug application has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response". To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE".

Sincerely yours,

(b)(5) [redacted]

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research