DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-849/S-039 and 18-571/S-019

aaiPharma
2320 Scientific Park Drive
Wilmington NC 28405

Attention: Colleen Johns
Regulatory Analyst

Dear Ms. Johns:

Please refer to your supplemental new drug applications dated May 27 and 23, received May 28 and 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bethine (terbutaline sulfate) Tablets, 2.5 mg and 5 mg and Brethine (terbutaline sulfate) Injection, 1 mg/mL.

These supplemental new drug applications provide for the addition of a Geriatric Use subsection to the Precautions section of the package insert.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted May 23, and 27, 2003, copy attached).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-849/S-039 and 18-571/S-019." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 827-5584.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Badrul Chowdhury

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