CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-625

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

AP letter
a-30-04

NDA 21-625

aaiPharma
Attention: Matthew Arnold
Regulatory Project Manager
AstraZeneca LP, agent for aaiPharma
1800 Concord Pike
Wilmington, DE 19803-8355

Dear Mr. Arnold:

Please refer to your new drug application (NDA) dated February 27, 2003, received March 3, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for M.V.I. Adult (multi-vitamin infusion), Unit Vial and Dual Vial.

We acknowledge receipt of your submissions dated December 17 and 22, 2003.

The December 22, 2003 submission constituted a complete response to our December 18, 2003 approvable letter.

This new drug application for M.V.I. Adult (multi-vitamin infusion) provides for an adult parenteral multivitamin product that contains vitamin K.

We completed our review of this application as amended. It is 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 enclosed labeling (package insert for the Unit Vial and Dual Vials submitted December 17, 2003, Dual Vial carton label submitted April 17, 2003 and Dual Vial labels submitted December 12, 2003, Unit Vial carton label submitted November 11, 2003, and Unit Vial label submitted April 17, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-625**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Holly Wieland, Regulatory Project Manager at (301) 827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES

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

/s/

Mary Parks
1/30/04 02:40:31 PM
for Dr. Orloff