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***APPLICATION NUMBER:***

**21-643**

**APPROVAL LETTER**

NDA 21-643

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 April 17, 2003, received April 18, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for M.V.I. Adult (multi-vitamin infusion), Pharmacy Bulk Package.

We acknowledge receipt of your submissions dated April 17, May 12, June 4, November 11, and December 22, 2003, and February 9 and 17 (secure email), 2004.

This new drug application provides for a Pharmacy Bulk Package, which is a new presentation of M.V.I. Adult (multi-vitamin infusion).

We have completed the 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 draft labeling (package insert and carton label submitted February 17, 2004, and immediate container labels submitted February 9, 2004). 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* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-643." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indication, 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, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 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, HFD-510  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosures