

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-625

MEDICAL REVIEW

MEDICAL OFFICER REVIEW

Division of Metabolic and Endocrine Drug Products (HFD-510)

Application #: 21,625

Application Type: New Drug Application (NDA)

Sponsor: aaiPharma

Proprietary Name: M.V.I. Adult

Investigator:

USAN / Established Multi-Vitamins for Name: Infusion

Category: Parenteral
multivitamins

Route of Administration: intravenous

Medical Reviewer: Jean Temeck, M.D.

Review Date: July 15, 2003

SUBMISSIONS REVIEWED IN THIS DOCUMENT

Document Date:	CDER Stamp Date:	Submission Type:	Comments:
February 27, 2003	March 3, 2003	NDA	

RELATED APPLICATIONS (if applicable)

Document Date:	APPLICATION Type:	Comments:
July 19, 1999	NDA 21-163	Multi-12 (Multiple Vitamins for Infusion) which is Baxter's product. This is the only other currently approved parenteral multivitamin product on the market for use in children and adults aged 11 and older.

REVIEW SUMMARY: This NDA application contains the reformulation of M.V.I. 12 to comply with the FRN of April 20, 2000. Specifically, the FRN requested increases in the amount of vitamins B₁, B₆, C and folic acid and the addition of vitamin K to the formulation indicated for adults and for children aged 11 years and above.

The application consists of only CMC information and labeling. All other pertinent data, including clinical data, is incorporated by reference to the existing adult multivitamin product, M.V.I.-12 (NDA 8-809, approved February 20, 1953) or the pediatric multivitamin product, M.V.I. Pediatric (NDA 18-920, approved April 6, 1983).

The sponsor is proposing a change in the product name from M.V.I.-12 to M.V.I. Adult. The sponsor is also proposing a single, combined PI for all 3 commercial presentations versus having 2 (one for unit dose and multiple dose and one for Univial presentations) as is currently approved for M.V.I.-12.

Comments to the proposed labeling are enclosed.

OUTSTANDING ISSUES: The proposed labeling changes to the sponsor's draft PI should be conveyed to the sponsor. A consult was sent to DMETS on March 27, 2003 to comment on the proposed name change.

RECOMMENDED REGULATORY ACTION:

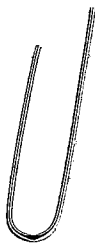
New Clinical Studies: _____ Clinical Hold _____ Study May Proceed

NDA, Efficacy/ Label Supplement: _____ X _____ Approvable _____ Not Approvable

SIGNATURES: Medical Efficacy Reviewer: Jean Temeck, M.D. Date: July 15, 2003

Medical Team Leader: _____ Date: _____

**Appears This Way
On Original**



6 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(5) Deliberative Process

✓ § 552(b)(5) Draft Labeling

Withheld Track Number: Medical- /

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

/s/

Jean Temeck
7/17/03 06:31:36 PM
MEDICAL OFFICER

Mary Parks
7/24/03 05:07:19 PM
MEDICAL OFFICER