

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-643

MICROBIOLOGY REVIEW

00.27.03

Product Quality Microbiology Review
Consult Review for HFD-510
25 August 2003

NDA: 21-625
21-643

Drug Product Name:

Proprietary: M.V.I. Adult™ Pharmacy Bulk Package (NDA 21-643)
M.V.I. Adult™ for infusion (NDA 21-625)

Non-proprietary: Multi-vitamin for infusion

Drug Product Classification: Parenteral

Review Number: 1

Subject of this Review:

Submission Date: 12 March 2003 and 17 April 2003

Receipt Date: 13 March 2003 and 21 April 2003

Consult Date: 25 March 2003 and 28 April 2003

Date Assigned for Review: 01 May 2003

Applicant/Sponsor:

Name: AstraZeneca, LP

Address: 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803

Representative: Kevin McKenna

Telephone: (302) 886-2742

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of sterility assurance.

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Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** Not Applicable
 2. **SUPPLEMENT PROVIDES FOR:** Not Applicable
 3. **MANUFACTURING SITE:** Westborough, MA
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** for intravenous administration
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGIC CATEGORY:** The product is used for total parenteral nutrition.
- B. **SUPPORTING/RELATED DOCUMENTS:** NDA 08-809, NDA 18-920
- C. **REMARKS:** The submission seeks approval for a product reformulation and a pharmacy bulk package format for the product.

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Executive Summary

- I. Recommendations**
- A. Recommendation on Approvability** – The application is recommended for approval on the basis of sterility assurance
 - B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable**
Not applicable
- II. Summary of Microbiology Assessments**
- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology**
The product is _____ filled.
 - B. Brief Description of Microbiology Deficiencies** – None
- III. Administrative**
- A. Reviewer's Signature** _____
 - B. Endorsement Block**
Paul Stinavage/25 August 2003
P.H. Cooney/
 - C. CC Block**
cc:
Original NDA 21-625 and NDA 21-643
HFD-510/Division File/NDA 21-625/NDA 21-643/E. Galliers

2 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Paul Stinavage

8/27/03 08:19:29 AM

MICROBIOLOGIST

Product reformulation and pharmacy bulk package.

Peter Cooney

8/27/03 01:36:14 PM

MICROBIOLOGIST