

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**21-594**

**Microbiology Review(s)**

**Product Quality Microbiology Review**  
**Review for HFD-110**  
**April 15, 2003**

**NDA: 21-594 and Amendment dated April 14, 2003.**

**Drug Product Name**

**Proprietary:**

**Non-proprietary: Amiodarone Hydrochloride Injection**

**Drug Product Classification: anti-arrhythmic**

**Review Number: 1**

**Subject of this Review**

**Submission Date: October 31, 2002, April 14, 2003**

**Receipt Date: November 8, 2002, April 14, 2003**

**Consult Date: December 17, 2002**

**Date Assigned for Review: January 2, 2003**

**Submission History (for amendments only):**

**Date(s) of Previous Submission(s):**

**Date(s) of Previous Micro Review(s):**

**Applicant/Sponsor**

**Name: International Medication Systems**

**Address: 1886 Santa Anita Ave.**

**South El Monte, CA 91733**

**Representative: Stephen A. Campbell, V.P. Reg. Affairs**

**Telephone: (626) 459-5253**

**Name of Reviewer: James L. McVey**

**Conclusion: This application is recommended for approval from a product quality microbiology perspective.**

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## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT:
  2. SUPPLEMENT PROVIDES FOR:
  3. MANUFACTURING SITE:  
International Medication Systems, Limited  
1886 Santa Anita Ave.  
South El Monte, CA 91733
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 50 mg/ mL, 3 mL and 18 mL in prefilled syringe.
  5. METHOD(S) OF STERILIZATION: —
  6. PHARMACOLOGICAL CATEGORY: Anti - arrhythmic
- B. SUPPORTING/RELATED DOCUMENTS:
- C. REMARKS: Not a generic because of new packaging configuration (pre-filled syringes).

filename: 21594r1

APPEARS THIS WAY  
ON ORIGINAL

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## Executive Summary

### I. Recommendations

- A. **Recommendation on Approvability** – This application is recommended for approval from a product quality microbiology perspective.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – None.

### II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – \_\_\_\_\_ drug product is \_\_\_\_\_ in \_\_\_\_\_ at IMS' South El Monte facility.
- B. **Brief Description of Microbiology Deficiencies** – No deficiencies were noted.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – Minimal risk is perceived from a product quality microbiology perspective.

### III. Administrative

- A. **Reviewer's Signature** \_\_\_\_\_ 
- B. **Endorsement Block**  
Review Microbiologist. J.L. McVey  
Microbiology Supervisor. P.H. Cooney
- C. **CC Block**  
cc:  
DFS  
HFD- 805/McVey/21594r1

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/s/

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James McVey  
5/1/03 09:40:26 AM  
MICROBIOLOGIST

Peter Cooney  
5/1/03 10:23:42 AM  
MICROBIOLOGIST