

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**75830**

**MICROBIOLOGY REVIEW**

OFFICE OF GENERIC DRUGS, HFD-640

Microbiology Review #1

January 11, 2001

A. 1. ANDA 75-830

APPLICANT: Faulding Pharmaceutical Company  
11 Commerce Drive  
Cranford, NJ 07016

2. PRODUCT NAME: Milrinone Lactate Injection 1 mg/mL

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Milrinone Lactate Injection 1 mg/mL is a sterile, aqueous solution and is manufactured as 10 mL and 20 mL fills in 10 mL and 20 mL glass vials.

4. METHOD(S) OF STERILIZATION: ( )

5. PHARMACOLOGICAL CATEGORY: Milrinone Lactate Injection is a positive inotrope and vasodilator indicated for short-term intravenous therapy of congestive heart failure.

B. 1. DATE OF INITIAL SUBMISSION: March 31, 2000  
Subject of this Review (Received April 3, 2000)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS:

DMF

DMF-

DMF-

DMF-

4. ASSIGNED FOR REVIEW: January 4, 2001

C. REMARKS: The subject drug product Milrinone Lactate Injection 1 mg/mL is manufactured by Faulding Pharmaceutical Company in Aguadilla, Puerto Rico. The subject drug product is (

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific

comments regarding the ( are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant".

( /S/ 1/29/01  
Marla Stevens-Riley, Ph.D.

@ 1/29/01

cc: Original **ANDA**  
Duplicate ANDA  
Division Copy  
Field Copy  
Drafted by M. Stevens-Riley, HFD 600 v:microrev\75-830  
Initialed by M. Fanning/A. High

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Micro Review #1

OFFICE OF GENERIC DRUGS, HFD-640

Microbiology Review #2

July 3, 2001

A. 1. ANDA 75-830

APPLICANT: Faulding Pharmaceutical Company  
11 Commerce Drive  
Cranford, NJ 07016

2. PRODUCT NAME: Milrinone Lactate Injection, 1 mg/mL

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Milrinone Lactate Injection, 1 mg/mL is a sterile, aqueous solution that is manufactured as a 50 mL fill in a 50 mL vial.

4. METHOD(S) OF STERILIZATION: ( )

5. PHARMACOLOGICAL CATEGORY: Milrinone Lactate Injection is a positive inotrope and vasodilator indicated for short-term intravenous therapy of congestive heart failure.

B. 1. DATE OF INITIAL SUBMISSION: March 31, 2000

2. DATE OF (GRATUITOUS) AMENDMENT: December 1, 2000  
Subject of this Review (Received December 4, 2000)

3. RELATED DOCUMENTS:

DMF-  
DMF-  
DMF-

4. ASSIGNED FOR REVIEW: June 27, 2001

C. REMARKS: The subject drug product Milrinone Lactate Injection, 1 mg/mL is manufactured by Faulding Pharmaceutical Company in Aguadilla, Puerto Rico. The subject drug product is filtered prior to filling to reduce bioburden and (

This submission includes 1 additional package size of 1 mg/mL as a 50 mL fill in a 50 mL vial. The March 31, 2000 microbiology submission has been reviewed and recommended.

D. CONCLUSIONS: The submission is recommended for approval on

the basis of sterility assurance. Specific comments regarding the ( are provided in "E. Review Notes".

MS  
Macla Stevens-Riley, Ph.D.

7-17-01

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7/17/01

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Drafted by M. Stevens-Riley, HFD 600 v:microrev\75-830a1  
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micro-Review #2