

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**75830**

**ADMINISTRATIVE DOCUMENTS**

**REVIEW OF PROFESSIONAL LABELING  
DIVISION OF LABELING AND PROGRAM SUPPORT  
LABELING REVIEW BRANCH**

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ANDA Number: **75-830**                      Dates of Submission: **November 22 and December 1, 2000**

Applicant's Name: **Faulding Pharmaceutical Inc.**

Established Name: **Milrinone Lactate Injection, 1 mg (base)/mL, 10 mL, 20 mL and 50 mL vials**

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**Labeling Deficiencies:**

**INSERT**

**1. DESCRIPTION**

Second paragraph, first sentence – Delete "lactate".

**2. ADVERSE REACTIONS**

**a. Cardiovascular Effects, first sentence**

- i. First line – Delete the extraneous mark between "milrinone" and "in".**
- ii. Second line – "ventricular" (lower case "v")**
- iii. Third line – Place "1" and "%" on the same line of text.**

**b. Other Effects - "Isolated spontaneous ... received; and in the post-marketing experience, liver function test abnormalities have been reported."**

**3. DOSAGE AND ADMINISTRATION**

The subsection headings "LOADING DOSE" and "MAINTENANCE DOSE" should be of the same prominence.

Please revise your insert labeling, as instructed above, and submit 4 draft copies for a tentative approval or 12 final printed copies of each labeling piece for a full approval of this application. If draft labeling is provided, please be advised that you will be required to submit 12 final printed copies of all labels and labeling at least 60 days prior to full approval of this application. In addition, you should be aware that color and other features (print size, prominence, etc) in final printed labeling could be found unacceptable and that further changes might be requested prior to approval.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes -

[http://www.fda.gov/cder/ogd/rld/labeling\\_review\\_branch.html](http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html)

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

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Wm Peter Rickman  
Acting Director  
Division of Labeling and Program Support  
Office of Generic Drugs  
Center for Drug Evaluation and Research

**REVIEW OF PROFESSIONAL LABELING  
DIVISION OF LABELING AND PROGRAM SUPPORT  
LABELING REVIEW BRANCH**

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ANDA Number: 75-830

Date of Submission: March 31, 2000

Applicant's Name: Faulding Pharmaceutical Inc.

Established Name: Milrinone Lactate Injection, 1 mg (base)/mL, 10 mL and 20 mL vials

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**Labeling Deficiencies:**

**1. GENERAL COMMENT**

Please revise your storage temperature recommendations throughout your labels and labeling as follows:

Store at controlled room temperature 15° to 30°C (59° to 86°F)(see USP).

**2. CONTAINER 10 mL and 20 mL**

- a. See GENERAL COMMENT above.
- b. Place an asterisk after the primary expression of strength (e.g. 10 mg/mL\*) and immediately before the "Each mL contains ..." statement.
- c. We encourage you to further differentiate your product strengths by boxing, contrasting colors, or some other means.

**3. CARTON 10 x 10 mL and 10 x 20 mL**

- a. See GENERAL COMMENT above and comments for CONTAINER.
- b. 10 x 20 mL - "Discard any unused portion." rather than "used"

**4. INSERT**

**a. GENERAL COMMENT**

Delete "lactate" in association with the established name throughout the insert labeling except in the TITLE, DESCRIPTION, INDICATIONS, CONTRAINDICATIONS, and HOW SUPPLIED sections.

**b. DESCRIPTION**

- i. First sentence - Delete the comma after "Injection".
- ii. "structural formula" rather than "structure"
- iii. "a molecular formula" rather than "an empirical formula"
- iv. Last paragraph, first sentence - "single-dose" (lower case "s")

**c. CLINICAL PHARMACOLOGY**

- i. Pharmacokinetics, first sentence - ... patients, milrinone had ... (relocate comma)

ii. Pharmacodynamics

A). First paragraph

- 1). First sentence - ... function, milrinone produced ... (add comma)
- 2). Last sentence - ... of the initiation ... (add "the")

B). Third paragraph - The sentence beginning "Milrinone has a ..." begins a new paragraph.

d. WARNINGS

The entire text of this section should be in bold print.

e. PRECAUTIONS

- i. Carcinogenesis, Mutagenesis, Impairment of Fertility, penultimate sentence - "... *in vivo* ..." (*italics*)
- ii. Pregnancy Category C - Delete the extra space between "both" and "8 mg/kg/day".

f. ADVERSE REACTIONS

Other Effects - The sentence beginning "Isolated spontaneous ..." begins a new paragraph.

g. HOW SUPPLIED

See GENERAL COMMENT (1) above.

Please revise your container labels and carton and insert labeling, as instructed above, and submit 4 draft copies for a tentative approval or 12 final printed copies for a full approval of this application. If draft labeling is provided, please be advised that you will be required to submit 12 final printed copies of all labels and labeling at least 60 days prior to full approval of this application. In addition, you should be aware that color and other features (print size, prominence, etc) in final printed labeling could be found unacceptable and that further changes might be requested prior to approval.

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Wm Peter Rickman  
Acting Director  
Division of Labeling and Program Support  
Office of Generic Drugs  
Center for Drug Evaluation and Research

## FIELD COPY CERTIFICATION

In accordance with 21 CFR 314.94(d)(5), as amended in Volume 58, Number 172 of the Federal Register, Faulding Pharmaceutical Co. is submitting a Field Copy of this Abbreviated New Drug Application as required. Furthermore, Faulding Pharmaceutical Co. certifies that the Field Copy is a true copy of the technical section contained in the Archival and Review Copies of this application as described in 21 CFR 314.94(a)(9).

01/05/01

Date

*K. Patel*

Kala Patel, M.S., R.Ph.  
Manager, Regulatory Affairs