CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75834

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: **75-834** Date of Submission: **March 31, 2000**

Applicant's Name: **Baxter Healthcare Corporation**

Established Name: **Milrinone Lactate in 5% Dextrose Injection (200 mcg base/mL) 100 mL and 200 mL**

Labeling Deficiencies:

1. CONTAINER (200 mcg/mL) 100 mL and 200 mL

   a. Delete the parentheses from "20 mg/100 mL" and "40 mg/200 mL"

   b. Revise the secondary expression of strength to read "200 mcg (0.2 mg) per mL*"

   c. Place an asterisk before the "Each mL contains ..." statement.

   d. Put periods at the end of the sentences in the text.

   e. Increase the prominence of "Rx only".

2. OVERWRAP (200 mcg/mL) 100 mL and 200 mL

   a. See comments (a), (b) and (c) under CONTAINER.

   b. Capitalize the statement "MUST NOT BE USED IN SERIES CONNECTIONS.".

3. INSERT

   a. GENERAL COMMENT

      Improve the overall print quality.

   b. DESCRIPTION

      "a molecular formula" rather than "an empirical formula"

   c. CLINICAL PHARMACOLOGY

      Sixth paragraph, last sentence - "... or shortly ..." rather than "... of shortly ..."

   d. PRECAUTIONS

      Carcinogenesis, Mutagenesis, Impairment of Fertility, penultimate sentence - "*in vivo*" (*italics*)

   e. DOSAGE AND ADMINISTRATION

      i. Add the following text to immediately follow the first table:

         The loading dose may be given undiluted, but diluting to a rounded total volume of 10 or 20 mL (see appropriate package insert for diluents) may simplify the visualization of the injection rate.

ii. Paragraph after second table - "... an improvement ..." rather than "... and improvement ..."

f. DIRECTIONS FOR USE

Preparation for Administration - "WARNING: DO NOT USE IN SERIES CONNECTIONS." (all upper case)

g. HOW SUPPLIED

If this drug product will be available in cases please specify how many per case in this section and also submit the case label.

Please revise your container labels and overwrap 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.

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

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.

/S/

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