CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75852

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 75-852 Date of Submission: April 28, 2000

Applicant's Name: Baxter Pharmaceutical Products Inc.

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

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Labeling Deficiencies:

1. GENERAL COMMENTS

   a. Revise the storage temperature recommendation throughout your labels and labeling as follows:

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

   b. Please clarify your "Mfd. for" statement on your labels and labeling. What is the meaning of "Manufactured for an affiliate of ..."? Please note that this wording does not appear amongst the qualifying phrases for a distributor appearing in 21 CFR 201.1(h)(5).

2. CONTAINER 10 mL, 20 mL, and 50 mL

   a. We encourage you to differentiate your total product strengths by boxing, contrasting colors, or some other means.

   b. Place an asterisk after the expression of strength [(1mg/mL)*] and before the "Each mL contains ..." statement.

   c. Space permitting, we encourage you to include the statement:

      "Discard unused portion after initial use."

   d. 10 mL and 20 mL

      Include the storage temperature recommendations.

3. CARTON 10 x 10 mL, 10 x 20 mL, 1 x 50 mL

   a. See comment 2(b).

   b. See GENERAL COMMENTS 1(a).

4. INSERT

   a. TITLE

      We encourage you to include "Rx only" beneath the title of the insert.

   b. DESCRIPTION

      Second paragraph - "a molecular" rather than "an empirical"

c. PRECAUTIONS

i. Decrease the prominence of the subsection title "Use In Acute Myocardial Infarction".

ii. Carcinogenesis, Mutagenesis, Impairment of Fertility, Penultimate sentence - "*in vivo*" (*italics*)

iii. Revise the subsection title as follows:

Pregnancy. Teratogenic Effects: Pregnancy Category C

d. HOW SUPPLIED

See GENERAL COMMENTS 1(a).

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.

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