CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75834

APPROVAL LETTER

ANDA 75-834

MAY 28 2002

Baxter Healthcare Corporation
Medication Delivery division
Attn: Marcia Marconi
Route 120 and Wilson Road
Round Lake, IL 60073

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Milrinone Lactate in 5% Dextrose Injection, 0.2 mg (base)/mL, packaged in 100 mL and 200 mL IntraVia® single-dose plastic containers for intravenous infusion.

Reference is also made to our Tentative Approval letter dated October 30, 2001, and to your amendments dated March 1, and May 22 (2 submissions), 2002.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Milrinone Lactate in 5% Dextrose Injection, 0.2 mg (base)/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Primacor® in 5% Dextrose Injection, 0.2 mg (base)/mL, of Sanofi Synthelabo, Inc.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 75-834
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-92

APPROVAL