DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-436/S-019
NDA 20-343/S-014

Sanofi-Synthelabo Inc.
Attention: Ms. Andrea Czeizinger
90 Park Avenue
New York, NY 10016

Dear Ms. Czeizinger:

Please refer to your supplemental new drug applications dated February 14, 2003, received February 14, 2003 (19-436/S-019) and April 2, 2003 (20-343/S-014), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primacor (milrinone lactate) Injection (19-436) and Primacor (milrinone lactate) in 5% Dextrose Injection (20-343).

These "Changes Being Effected" supplemental new drug applications provide for final printed labeling revised as follows:

1. Under **ADVERSE REACTIONS, Cardiovascular Effects**, a new sentence has been added that reads as follows:

   In the post-marketing experience, there have been rare cases of "torsades de pointes" reported.

2. Under **ADVERSE REACTIONS, Other Effects**, the adverse events of "anaphylactic shock" and "skin reactions such as rash" have been added to the second paragraph of this subsection.

   The second paragraph now reads as follows:

   Isolated spontaneous reports of bronchospasm and anaphylactic shock have been received; and in the post marketing experience, liver function test abnormalities and skin reactions such as rash have been reported.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package inserts included in your submissions dated February 14, 2003). Accordingly, the supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton
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