DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-436/S-022
NDA 20-343/S-021

sanofi-aventis U.S. LLC
Attention: John Cook
300 Somerset Corporate Boulevard
Bridgewater, N.J., 08807-0977

Dear Mr. Cook:

Please refer to your supplemental new drug applications dated May 7, 2007, received May 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 19-436 (SN 022) Primacor (milrinone lactate) Injection and NDA 20-343 (SN 021) Primacor (milrinone lactate) in 5% Dextrose Injection.

These "Changes Being Effected" supplemental new drug applications provide for revision of the **DESCRIPTION, DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the labeling. Sanofi-aventis intends to discontinue the sale of the PRIMACOR Injection, l mg/mL strength, family of products, but will continue to market the PRIMACOR Flexible Container 200 mcg/mL in 5% Dextrose Injection family of products. The labeling in the **DESCRIPTION, DOSAGE AND ADMINISTRATION and HOW SUPPLIED** sections have been revised, removing the mention of the PRIMACOR 1 mg/ml strength products. The labeling has also been updated to list the current available product in the **HOW SUPPLIED** section.

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR.314.50(1)] in structured product labeling (SPL) format submitted on May 7, 2007 and with the minor editorial revision listed below.

The title section should be changed from:

PRIMACOR®
MILRINONE LACTATE INJECTION

to:

PRIMACOR®
MILRINONE LACTATE INJECTION
IN 5% DEXTROSE INJECTION

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 call Mr. John David, Regulatory Project Manager, at (301) 796-1059.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal 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/

Norman Stockbridge

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