DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-436/S-021
NDA 20-343/S-020

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

Dear Mr. Cook:

Please refer to your supplemental new drug applications dated December 12, 2006, received December 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 19-436 (SN 021) Primacor (milrinone lactate) Injection and NDA 20-343 (SN 020) Primacor (milrinone lactate) in 5% Dextrose Injection.

These "Changes Being Effected" supplemental new drug applications provides for the revision of the PRECAUTIONS and the ADVERSE REACTIONS section to include statements regarding infusion site reactions. Also the HOW SUPPLIED section was revised to reflect the current company information.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 12, 2006.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA.

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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