DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-273/S-060

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 application dated April 29, 2008, received April 30, 2008, submitted under section 505(b) (1) of the Federal Food, Drug, and Cosmetic Act for Lasix (furosemide) 20, 40 and 80 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the ADVERSE REACTIONS section of the labeling.

We have completed our review of this application and it is 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 April 29, 2008.

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

10/22/2008 07:46:03 AM