DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-768/S-002

Citigroup Biomedical Imaging Center
Weill Medical College of Cornell University
Attention: Dr. Shankar Vallabhajosula
Professor of Radiochemistry and Radiopharmacy in Radiology
516 East 72nd Street
New York, NY 10021

Dear Dr. Vallabhajosula:

Please refer to your supplemental new drug application dated November 16, 2006, received November 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fludeoxyglucose F18 Injection, 10-100 mCi/mL at the end of synthesis (EOS).

This "Changes Being Effected" supplemental new drug application provides for labeling changes to conform to USP.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Robert Hummel, Regulatory Project Manager for Quality, at (301) 796-1981.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel

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