DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21870/S-009

APPROVAL LETTER

The Feinstein Institute for Medical Research
Attention: Thomas Chaly, Ph.D.
350 Community Drive
Manhasset, NY 11030

Dear Dr. Chaly:

Please refer to your Supplemental New Drug Application (sNDA) dated August 14, 2014, received August 15, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fludeoxyglucose F 18 Injection.

This "Prior Approval" supplemental new drug application provides for an increase in the concentration of the drug product from 20-300mCi/mL to 20-400mCi/mL.

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

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, call Rebecca McKnight, Regulatory Project Manager, at (301) 796-1765.

Sincerely,

Ramesh Raghavachari -S

Digitally signed by Ramesh Raghavachari -S
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Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX
Division of New Drug Quality Assessment III
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