DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-141/S-029

GE Healthcare
Attention: Susan Elliott, Senior Manager
Regulatory and Labeling Compliance
Regulatory Affairs
101 Carnegie Center
Princeton, New Jersey 08540

Dear Ms. Elliott:

Please refer to your supplemental new drug application dated March 2, 2007, received March 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MDP Multidose – MDP Multidose Utilipak (Kit for the Preparation of Tc99m Medronate Injection).

We acknowledge receipt of your submissions dated March 2 and September 4, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes in the Contraindications, Warnings, and Adverse Reactions sections of the current package inserts to strengthen the wording to reflect hypersensitivity to the drug and adverse reactions.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), submitted September 4, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-141/S-029**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

If you have any questions, call Rene Tyson, Regulatory Project Manager, at (301) 796-1476.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure(s)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rafel Rieves

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