DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-707/S-010

GE Healthcare
Attn: Susan White,
Manager, Regulatory and Labeling Compliance
Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. White:

Please refer to your supplemental new drug application dated July 23, 2004, received July 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Indium DTPA In 111 (Pentetate Indium Disodium In 111).

This supplemental new drug application provides for the addition of a 'Geriatrics Use' subsection to the PRECAUTIONS section of the package insert to comply with the final rule 21 CFR 201.57 (f)(10)(A). We also note that it is compliant with 21 CFR 201.57(f)(10)(iii)(B) and reads as follows:

> "Clinical studies of Indium DTPA In 111 did not include sufficient numbers of subjects aged 65 and over to determine whether they responded differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the lower end of the dosing range, reflection the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.
>
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken or other drug therapy."

We completed our review of this application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (package insert submitted July 26, 2004).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-707/SLR-010." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Diane C. Smith, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., MBA
Division Director for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
Office of Drug Evaluation III
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/

Kyong Kang
9/21/04 04:19:04 PM
Signing for Dr. George Mills