DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-829/SLR-019

GE Healthcare
Attention: Susan Elliott
Senior Manager, Regulatory and Labeling Compliance
101 Carnegie Center
Princeton, NJ 08540-6231

Dear Ms. Elliott:

Please refer to your supplemental new drug application dated December 17, 2004, received December 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ceretec™ (Technetium Tc99m Exametazine).

We acknowledge receipt of your submissions dated April 27, May 27 and June 8, 2005. We also refer to the teleconference between you and Patricia Stewart on June 7, 2005.

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) published in the federal Registry August 27, 1997.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter to add the following verbiage to the package insert:

> "Of 207 subjects in clinical studies of Ceretec™, 103 (50%) were 65 and over, while 25 (12%) were 75 and over. No overall differences in safety were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
>
> 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 in dose selection, and it may be useful to monitor renal function."

Please submit the copies of final printed labeling (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 but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For

administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-829/SLR-019." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Patricia A. Stewart, Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Radiopharmaceutical Drug Products
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/

George Mills
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