DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-630/SLR-013

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

Dear Ms. Elliott:

Please refer to your supplemental new drug application dated December 21, 2004, received December 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for **Sodium Iodide I 123 (Sodium Iodide I-123 Capsules).**

We acknowledge receipt of your submissions dated December 21, 2004, and April 27, 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)(ii)(A). We also note that it is compliant with 21 CFR 201.57 (f)(10)(iii)(B) and reads as follows:

> **"Clinical studies of Sodium Iodide I 123 (Sodium Iodide I-123 Capsules) did not include sufficient numbers of subject aged 65 and over to determine whether they respond 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 low end of the dosing range, reflecting 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 in dose selection, and it may be useful to monitor renal function."**

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 December 21, 2004.

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 17-630/SLR-013**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Renee C. Tyson, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., MBA
Director, 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/

George Mills
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