



NDA 18-110/SLR-012

GE Healthcare
Attn: Susan Elliott
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. Elliott:

Please refer to your supplemental new drug application dated November 30, 2004, received December 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thallous Chloride TI 201 (Thallous Chloride TI 201 Injection).

We acknowledge receipt of your submissions dated November 30, 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)(A). We also note that it is compliant with 21 CFR 201.57 (f)(10)(iii)(B) and reads as follows:

“Clinical studies of Thallous Chloride TI 201 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 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 November 30, 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 18-110/SLR-012.**" 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 Diane C. Smith, 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/

Kyong Kang
5/12/05 03:07:25 PM
Signing for George Mills, MD.