DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-150/SCS-020

Mallinckrodt Inc.
Attention: James W. Brodack, Ph.D.
Regulatory Affairs Manager
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Dr. Brodack:

Please refer to your supplemental new drug application dated October 15, 2003, received October 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thallous Chloride Tl 201 Injection.

We acknowledge receipt of your submission dated October 16, 2003.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes to 1) the process for the manufacture of Code L201B Thallous Chloride Tl 201 ((b)(4)----------(b)(4)---------- ---------- ---------- (b)(4)----------), and 2) the maximum Calibration period for Code 120 Thallous Chloride Tl 201 Injection (extension of the maximum Calibration period from (b)(4)----- ----------days post manufacture date).

We completed our review of this application. 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 submitted labeling (package insert submitted October 15, 2003).

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 18-150/SCS-020." 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 the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lynn Panholzer, Pharm.D., Regulatory Project Manager, at (301) 827-3132.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products (HFD-160)
DNDC II, Office of New Drug Chemistry
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/

Eldon Leutzinger

4/16/04 12:14:16 PM