DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-243/SCS-025

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

Dear Dr. Brodack:

Please refer to your supplemental new drug application dated June 17, 2004, received June 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultra-TechneKow DTE (Technetium Tc99m Generator).

We acknowledge receipt of your submission dated August 19, 2004.

This supplemental new drug application provides for a change to the Calibration period for Ultra-TechneKow® DTE (Technetium Tc99m Generator) and a change to the Calibration Reference time. As a result of the changes in the Calibration period and the Reference time, the approved label activity will also change.

We completed our review of this application and it 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 enclosed labeling (text for the package insert) submitted August 19, 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 17-243/SCS-025." 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 Patricia Stewart, Regulatory Project Manager, at (301) 827-7496.

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

Enclosure: package insert

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

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