DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-243/SLR-028

Mallinckrodt Inc.
Attn: William Reinhart
Sr. Regulatory Affairs Associate
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Reinhart:

Please refer to your supplemental new drug application dated October 24, 2005 received October 25, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultra-TechneKow® DTE (Technetium Tc 99m Generator).

We acknowledge receipt of your submission dated October 25, 2005.

This supplemental new drug application provides for the following labeling changes:

1. Instructions for the use of the elution alignment adapter, a new component for customer use (Preparation and Expired Generator Disposal Section).
2. The removals of the reference to a lead glass window in the Auxiliary Shield (Preparation Section) and a lead glass window in the Elution Shield (Elution Section).
3. Proposed changes providing clarification to instructions in both the Preparation and Elution Sections.
4. Proposed changes to the Expired Generator Disposal Section which includes references to the alignment adapter and minor text change.

We completed our review of this application, as amended. 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 text for the package insert submitted October 24, 2005.

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 17-243/SLR-028**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Tiffany Brown, Regulatory Health Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and
Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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
3/27/2006 04:14:28 PM