



NDA 17-243/SCS-022

Tyco/Healthcare-Mallinckrodt  
Attention: James W. 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 December 28, 2001, received December 31, 2001, 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 submissions dated June 13 and 17, July 12 and December 10, 2002. Your submission of December 10, 2002, constituted a complete response to our June 5, 2002, action letter.

This supplemental application proposed redesign of the DTE Elution Hood Assembly to address a potential radiation safety issue raised by the Nuclear Regulatory Commission. In addition to the changes in the design of the EHA, this supplement provided for the following text to be deleted from the ELUTION section #3 of the package insert:

*“When smaller elution volumes are required, the elution may be interrupted by rotating the vial shield a quarter turn clockwise and pushing downwards for a few seconds (this stops the elution and fills the remainder of the vial with sterile air).”*

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 10, 2002

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, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Patricia A. 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

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/s/

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Eldon Leutzinger  
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