DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 22 1998

TRANSMITTED VIA FACSIMILE

Laura Navarre
Senior Regulatory Affairs Associate
Mallinckrodt Medical, Inc.
675 McDonnell Blvd.
St. Louis, MO 63434

Re: NDA 20-314
OctreoScan (kit for the preparation of indium In-111 pentetreotide)
MACMIS ID # 6861

Dear Ms. Navarre:

This letter refers to Mallinckrodt Medical, Inc.'s (Mallinckrodt) submissions, dated March 27, and April 15, 1998, of promotional materials under cover of Form FDA 2253 for OctreoScan. The submissions included a journal advertisement identified as MI22701 and a sales aid identified as MI22700. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these promotional materials and has concluded that they are lacking in fair balance or are otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

> The advertisement and promotional labeling fail to present any information relating to the product's side effects and contraindications, or other risk information. The approved product labeling for OctreoScan includes important warnings and precautions regarding the use of OctreoScan. This risk-balancing information should be presented in a manner reasonably comparable in prominence and readability as the presentation of information relating to the effectiveness of the drug.

Mallinckrodt should immediately cease the dissemination of these violative promotional materials and all similar promotional materials that are lacking in fair balance.

Mallinckrodt should respond to DDMAC in writing regarding this matter no later than August 5, 1998.

Please direct your correspondence to undersigned by facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications HFD-

40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Mallinckrodt that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6861 and NDA 20-314.

Sincerely,

/S/

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications