



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-

Laura Navarre  
Mallinckrodt Medical, Inc.  
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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