



FOI

Food and Drug Administration
Rockville MD 20857

APR 15 1999

TRANSMITTED VIA FACSIMILE

Mary E. Hamilton
Manager, Regulatory Affairs
Mallinckrodt, Inc.
PO Box 5840
St. Louis, MO 63134

RE: **ANDA 87-388**
MD-Gastroview (diatrizoate meglumine and diatrizoate sodium solution, U.S.P.)
MACMIS # 7856

Dear Ms. Hamilton:

This letter is in reference to Mallinckrodt, Inc.'s (Mallinckrodt) submission, dated February 5, 1999, of promotional materials under cover of Form FDA 2253 for MD-Gastroview. The submission included a sales aid identified as CM09898. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed the sales aid and has concluded that it is lacking in fair balance or otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

This advertisement fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Although you have presented the warning "not for parenteral use," the information is presented in a manner that minimizes its importance and readability. Further, you have made numerous claims regarding safety and efficacy for the product, but have not provided information regarding the numerous warnings, precautions, and adverse reactions associated with the use of the drug. In general, claims should be accompanied by information about the most serious and the most common adverse events associated with the use of the drug.

DDMAC requests that Mallinckrodt immediately cease the dissemination of this violative sales aid and any other violative promotional materials that are lacking in fair balance. You should respond to DDMAC regarding this violation by April 29, 1999, providing the date Mallinckrodt ceased the dissemination of this and any other violative promotional materials.

Mary E. Hamilton
Mallinckrodt, Inc.
ANDA 87-388

page 2

If you have any questions, please contact me by facsimile at (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 # 7856 and NDA.

Sincerely,

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