



FOI

Food and Drug Administration  
Rockville MD 20857

MAR 31 1999

**TRANSMITTED VIA FACSIMILE**

Madhu Anant  
Associate Director, Regulatory Affairs  
Bracco Diagnostics, Inc.  
107 College Road  
Princeton, NJ 08543-5225

RE: **NDA 20-131**  
Prohance (gadoteridol injection)  
MACMIS # 7798

Dear Mr. Anant:

This letter is in reference to Bracco Diagnostics, Inc.'s (Bracco) submission, dated March 12, 1999, of promotional materials under cover of Form FDA 2253 for Prohance. The submission included three promotional cards identified as 99-0201T, 99-0202T, and 99-0203T. 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

This promotional labeling 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. DDMAC acknowledges that you have presented the warning regarding caution in patients with deoxygenated sickle erythrocytes, and the precaution regarding patients with renal insufficiency with and without hepatic impairment. However, you fail to present this information with a prominence and readability reasonably comparable to the claims for Prohance. Thus, DDMAC requests that Bracco immediately cease the dissemination of these violative promotional materials and any other violative promotional materials that are lacking in fair balance. Bracco should respond to DDMAC regarding this violation by April 14, 1999, providing the date it ceased the dissemination of these and any other promotional materials.

Madhu Anant  
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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 Bracco that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7798 and NDA 20-131.

Sincerely,

/S/

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