

MAR 31 1999

## TRANSMITTED VIA FACSIMILE

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

RE: **NDA 20-773**  
SonoRx (simethicone coated cellulose suspension 7.5mg/ml)  
MACMIS # 7797

Dear Mr. Anant:

This letter is in reference to Bracco Diagnostics, Inc.'s (Bracco) submission, dated March 8, 1999, of promotional materials under cover of Form FDA 2253 for SonoRx. The submission included two brochures identified as 98-011750-12 and 98-011751-2 and a reimbursement card identified as 98-011750-11. 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

All these promotional materials fail to present **any** information relating to side effects and contraindications or other risk information (emphasis added). This required balancing risk 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. DDMAC notes that the approved product labeling for SonoRx includes warnings, and precautions regarding vomiting and nausea associated with the use of this product. Further, the labeling warns about the unknown effects of SonoRx on human peritoneal tissues. DDMAC suggests that Bracco include information from its labeling regarding these safety concerns in addition to the incidence of adverse events associated with the use of the drug.

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.

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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 # 7797 and NDA 20-773.

Sincerely,

/S/

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