



OCT 21 1997

**TRANSMITTED VIA FACSIMILE**

Marcia Marconi  
Vice President  
Baxter Healthcare Corporation  
Route 120 and Wilson Road  
Round Lake, IL 60073

**RE: NDA 19-520  
Travasol (Amino Acid) Injections in Dextrose Injection in Quick Mix Dual  
Chamber Container  
MACMIS ID # 5927**

Dear Ms. Marconi:

This letter is in reference to Baxter Healthcare Corporation's (Baxter) submission, dated September 17, 1997, of promotional materials under cover of Form FDA 2253 for Travasol. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed Baxter's submission of a brochure identified as 800050 and considers the promotional material to be false and/or misleading in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Fair Balance

The brochure titled, "Nutritional Support Using Quick Mix with Electrolytes" fails to present any information relating to side effects and contraindications or other balancing risk information related to the use of Travasol. In the brochure, Baxter presented the indication, dosage regimens, and benefits of Travasol, but did not include balancing risk information associated with the use of the drug.

DDMAC requests that Baxter immediately discontinue the use of this brochure and any other promotional materials that are false and/or misleading and lack fair balance. Baxter should add balancing risk information to all promotional materials that make product benefit claims but lack fair balance. This balancing risk information should be presented in a manner comparable in prominence and readability as the presentation of information relating to the effectiveness of the drug.

We request that Baxter respond to DDMAC by November 4 1997, regarding this issue. If you have any questions, please contact me by telephone at (301) 827-2831, by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing,

**Marcia Marconi, Vice President  
Baxter Healthcare Corporation  
NDA 19-520**

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**Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville,  
MD 20857. DDMAC reminds Baxter that only written communications are considered  
official.**

**In all future correspondence regarding this matter, please refer to MACMIS # 5927 and  
NDA 19-520.**

**Sincerely,**

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