DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JAN 29 1997

TRANSMITTED VIA FACSIMILE

John D'Angelo, M.S., R.Ph.
Director, Regulatory Affairs
McGaw, Inc.
2525 McGaw Avenue
Irvine, CA 92713-9791

RE: NDA 19-018
TrophAmine (6% and 10% Amino Acid Injections)
MACMIS ID # 5099

Dear Mr. D'Angelo:

This letter is in reference to McGaw, Inc.'s (McGaw) submission, dated January 7, 1997, of promotional materials under cover of FDA Form 2253 for TrophAmine (6% and 10% Amino Acid Injections). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed McGaw's submission of a nutritional newsletter (Y08-550-775) and considers the promotional material to be false and/or misleading and in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Fair Balance

"The McGaw Messenger- A Nutritional Newsletter" fails to present any information relating to side effects and contraindications or other balancing risk information related to the use of TrophAmine. In the newsletter, two practitioners present their experiences with the use of TrophAmine and make numerous claims regarding the benefits of using the drug such as, "TrophAmine was introduced because of concerns about the safety of elevated plasma concentrations of these amino acids [until recently, PN for preterm infants involved the use of amino acid solutions designed by adults]" and "we continue to use it because our clinical experience with lack of adverse events, and the literature continuing to show a possible benefit over other formulations." Further, on page 5 of the newsletter, McGaw makes claims regarding the benefits of using the ClearChoiceDCB Dual Chamber Mixing Bag for home patients on TPN. DDMAC requests that McGaw add balancing risk information to all future copies of this newsletter and to any similar 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 McGaw respond to DDMAC by February 12, 1997, identifying its corrective action regarding these promotional materials. 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, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds McGaw that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 5099 and NDA 19-018

Sincerely,

Warren Rumble

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

troph.nov

Drafted:	W Rumble	01-28-97
Comment:	Sherman	01-29-97
Concur:	T Abrams	01-29-97

WR 1/29/97

cc. HFD-240 NDA 19-018
HFD-240 chron/Rumble/Abrams
HFD-510 NDA 19-018
HFD-510 mo/cso-McCort

MACMIS ID#	5099
MACMIS Type Code:	LETT
MACMIS Action Code:	VIOL
2253 ID#:	48116
Material ID#:	Y08-550-775
Due Date:	Feb. 12, 1997
Close Out:	NO
FOI Status	releasable