DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 15 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 18-582
ProcalAmine (3% Amino Acid and 3% Glycerine Injection with Electrolytes)
MACMIS ID # 5689

Dear Mr. D'Angelo:

This letter is in reference to McGaw, Inc.'s (McGaw) submission, dated June 4, 1997, of promotional materials under cover of Form FDA 2253 for ProcalAmine. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed McGaw's submission of a nutritional newsletter identified as Y08-550-838 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 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 ProcalAmine. In the newsletter, Dr. Carol Ireton-Jones presents two patient case experiences with the use of ProcalAmine in peripheral parenteral nutrition (PPN) and concludes treatment with the drug was beneficial. The conclusions included: (1) no problems occurred such as in line infiltration or infection; (2) there was improvement in the coccyx decubitus ulcer from stage IV to stage III indicating healing had occurred; (3) as a result the patient regained strength; (4) PPN is relatively simple and a less invasive method of providing temporary nutrition; and, (5) PPN is a practical and useful alternative for patients requiring temporary, supplemental nutritional support in the hospital, home, or long-term care. McGaw presented benefits of ProcalAmine, but did not include balancing risk information associated with the use of the drug.

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** (emphasis added). 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.

DDMAC made this same request to McGaw regarding this newsletter on February 5, 1997. DDMAC requested 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 (emphasis added)**. In its response to DDMAC's letter, McGaw stated that it would discontinue all further distribution of the McGaw Messenger Nutritional Newsletter (regarding TrophAmine) and that all future materials regarding TrophAmine would contain fair balance. DDMAC is concerned that the issue of fair balance that was already addressed regarding a previous edition of the McGaw Messinger Nutritional Newsletter needs to be addressed again regarding this issue of the newsletter. McGaw should incorporate fair balance in the promotional materials for all of its products.

McGaw should immediately discontinue the use of this newsletter and any other promotional materials that are false and/or misleading and lack fair balance. We request that McGaw respond to DDMAC by August 29, 1997, identifying its corrective action regarding these promotional materials. In its response, McGaw should submit two copies of all similar promotional materials and tell which of these materials it is discontinuing, and which materials it will continue to use. 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 # 5689 and NDA 18-582.

Sincerely,

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