DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

APR 10 1997

TRANSMITTED BY FACSIMILE

Donald R. Peckels
Associate Director
U.S. Regulatory
G.D. Searle & Co.
4901 Searle Parkway
Skokie, IL 60077

Re: NDA 18-841
Daypro (oxaprozin) Tablets
MACMIS ID #5308

Dear Mr. Peckels:

This letter is in reference to G.D. Searle Co.'s (Searle) submission of promotional materials under cover of FDA Form 2253 for Daypro (oxaprozin) Tablets. These materials included promotional poster A97DA13101W-1. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards this poster to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, DDMAC is concerned that Searle makes claims that a "[n]ew study shows no clinically significant impact on platelets" and "[s]mall effect on ex vivo stimulated platelet aggregation." These statements are based on a study of 21 healthy volunteers. However, these statements are inconsistent with the approved product labeling and diminish the precaution statement that, "Oxaprozin, like other NSAIDs, can affect platelet aggregation and prolong bleeding time. Daypro should be used with caution in patients with underlying hemostatic defects or in those who are undergoing surgical procedures where a high degree of hemostasis is needed."

The number of patients evaluated in the clinical trials on which the approved product information is based is much greater than the 21 healthy volunteers in the study used by Searle to support these claims. Moreover, such false and/or misleading statements by Searle may place patients requiring a high degree of hemostasis at unnecessary risk.

Searle should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter. Searle should submit a written response to DDMAC on or before April 25, 1997, describing the steps taken

to ensure that the use of these materials, and all materials with the same or similar message, have been discontinued.

If Searle has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Searle that only written communications are considered official.

In all future correspondence regarding this matter, please refer to both the NDA number and the MACMIS ID #5308.

Sincerely,

Stephen W. Sherman

Stephen W. Sherman, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising & Communications

File name: relanov.409

Draft: Sherman - 4/9/97
Comment: WRumble - 4/9/97
Revised: Sherman - 4/9/97
Comment: TAbrams - 4/10/97
Revised: Sherman - 4/10/97
Concur: TAbrams - 4/10/97

cc:
HFD-40/NDA 18-841
HFD-40/Chron/Sherman/Abrams
HFD-550/NDA 18-841
HFD-550

MACMIS File Id #
MACMIS Type Code: LETT
MACMIS Action Code: VIOL

Due Date: April 25, 1997
Close Out: **NO** (circle one)

FOI Status: **RELEASEABLE**