DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 16 1997

TRANSMITTED BY FACSIMILE

Donald R. Peckels
Associate Director
Regulatory Affairs
G.D. Searle & Co.
4901 Searle Parkway
Skokie, Illinois 60017

Re:
Celecoxib
MACMIS ID#5541

Dear Mr. Peckels:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed G.D. Searle & Co.'s (Searle) promotional material for celecoxib on the Internet and has determined that these promotional materials are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specifically, these promotional materials promote an unapproved new drug.

In Searle's Internet site (http://www.searlehealthnet.com), "HealthNet, Products in Development", the company states that its investigational drug celecoxib "does not interfere with protective prostaglandins in the stomach, intestines and kidney." Furthermore, the statement that celecoxib does not interfere with protective prostaglandins combined with the statement that commonly prescribed arthritis medications cause gastrointestinal bleeding, suggests that celecoxib does not cause gastrointestinal bleeding.

Searle presents a press release at its Internet site that states that the results of a Phase II study support the product's safety and efficacy in the treatment of osteoarthritis. Moreover, Searle's press release suggests that celecoxib blocks inflammation, without interfering with the protective role of cyclooxygenase enzymes (COX-1) in the stomach. However, Searle has not demonstrated that celecoxib does not interfere with prostaglandins in the stomach, intestines, or kidney nor that it does not cause gastrointestinal bleeding.

Additionally, Searle's press release uses promotional statements such as, "EXPERTS OPTIMISTIC ABOUT BREAKTHROUGHS IN ARTHRITIS" and describes its investigational COX-2 inhibitor as "a medication now in Phase III clinical trials that is being heralded by many

researchers as a potential breakthrough in arthritis therapy". The use of such statements are clearly violative of the Act and its implementing regulations.

It is important to contrast Searle's activities in this matter with the non-promotional exchange of scientific information concerning a drug prior to FDA approval. The Agency does not wish to restrict the full exchange of scientific information and does not seek to regulate activities that are non-promotional. It has been DDMAC's longstanding position that individual, non-promotional responses by pharmaceutical companies to specific, unsolicited requests for scientific information (including information on unapproved uses) from health care professionals will not generally be regarded as promotional labeling. However, the materials disseminated may not commercialize the drug before it is approved for commercial distribution. As previously stated in our letter dated June 23, 1997.

Searle should delete all references to celecoxib in its Internet site, including the press release, concerning the benefits of the drug that suggest that it is safe and effective in the treatment of arthritis and that it is selective in blocking COX-2 while not interfering with COX-1, when such has not been demonstrated by substantial evidence.

If you have any questions, please contact me by facsimile (301) 594-6771 or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS number 5541, in addition to the NDA number.

Sincerely,

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