DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED BY FACSIMILE

Winifred M. Begley
Director
Regulatory Affairs
G.D. Searle & Co.
4901 Searle Parkway
Skokie, Illinois 60017

DEC 08 1998

RE:
Celebra (celecoxib) capsules
MACMIS ID #7167

Dear Ms. Begley:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for the unapproved drug Celebrex™ (celecoxib) that are in violation of the Federal Food Drug and Cosmetic Act (Act) and its implementing regulations. DDMAC specifically refers to the press release issued on November 12, 1998, regarding the announcement of Phase III trials presented by Searle at the American College of Rheumatology 62nd National Scientific Meeting. DDMAC finds the press release violative for the following reasons.

Pre-Approval Promotion

Based on a review of the press release Searle has disseminated concerning Celebrex™, DDMAC has concluded that Searle is making promotional representations concerning the efficacy and safety of Celebrex™. The regulations promulgated pursuant to the Food Drug and Cosmetic Act (Act) at 21 CFR 312.7 state, among other things, that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. The regulation distinguishes promotional representations from the full exchange of scientific information concerning the drug. This exchange is limited to presentations of scientific findings of the clinical research. As noted below, the following representations are promotional in nature and exceed the presentation of scientific findings:

- "As Effective as Naproxen and Diclofenac but with a Gastrointestinal Safety Profile Similar to Placebo"

- "Searle and Pfizer's investigational drug, relieved the signs and symptoms of arthritis as effectively as the full therapeutic doses of two of the most widely prescribed non-steroidal anti-inflammatory (NSAID) pain relievers in use today, but with a gastrointestinal (GI) safety profile similar to placebo"

- "Safety Profile Showed no Significant GI Safety Differences from Placebo"

- "In Clinical studies, celecoxib was as effective as the widely used NSAID naproxen in both RA and OA, but with a superior safety profile"

Requested Actions

Searle should immediately discontinue its use of promotional materials that contain these or similar claims or representations. Searle should submit a written statement of Searle's intent to comply with the discontinuation of this and any other like material.

Your written response should be received by DDMAC no later than December 15, 1998. You should direct this response to the undersigned by facsimile at (301) 594-6771, or by mail to the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications HFD-40, Rm 17-B-20, 5600 Fischers Lane, Rockville, MD 20875. DDMAC reminds Searle that only written communications are considered official. In all future correspondence regarding this matter please refer to the MACMIS ID #7329 in addition to the NDA number.

Sincerely,

John C. Markow, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications