DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

F.O.I

SEP - 9 1999

TRANSMITTED VIA FACSIMILE

Janine L. Holmes
Regulatory Manager—Promotion Review
Pharmacia & Upjohn, Inc.
7000 Portage Road
Kalamazoo, Michigan 49001-0199

RE: NDA 20-571
Camptosar Injection (irinotecan HCl injection)
MACMIS ID# 8200

Dear Ms. Holmes:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional labeling materials for Camptosar (irinotecan HCl injection) disseminated by Pharmacia & Upjohn (P&U) that violate the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Reference is made to three convention panels (USX4261.00), submitted under cover of Form FDA 2253 on April 30, 1999. DDMAC has reviewed these panels and has determined that one of them contains a promotional claim that is misleading. DDMAC requests that the use of the above referenced materials and those containing similar promotional claims or presentations cease immediately.

Misleading Efficacy Claim

The bolded statement, "**Patient Well-being**" preceding a presentation of symptom subscale results is misleading because this presentation implies a greater benefit (an overall effect on quality of life or well-being) than has been demonstrated by substantial evidence. Previously, during the initial launch period, DDMAC provided comments relative to the issue of using the phrase, "Quality of Life" in advertising and promotional materials. The phrase, "Patient Well-being" is synonymous with "quality of life". Although Camptosar showed improvements in 4 of 9 symptom subscales, 4 other symptom subscales revealed no statistically significant differences between the treatment arms. In fact, patients on Camptosar even had significantly more diarrhea than those on Best Supportive Care. P & U's broad claim of "Patient Well-being" is not supported by substantial evidence and is therefore, misleading.

P&U should immediately cease using this and all other promotional materials for Camptosar that contain the same or similar claims or presentations. P&U should submit a written response to DDMAC, on or before September 23, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, P&U should include a list of all promotional materials that were discontinued, and the discontinuation date.

P&U should direct its response to the undersigned 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 P&U that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 8200 and NDA 20-571.

Sincerely,

/S/

Michael A. Misocky ~~R.Ph., J.D.~~
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications