DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE JUN - 7 2000

Stephen W. Sherman
Director, Labeling and Advertising
Regulatory Affairs
ALZA Corporation
1010 Joaquin Road
Mountain View, CA 94039

RE: NDA 50-718
Doxil® (doxorubicin HCl liposome injection)
MACMIS ID# 9041

Dear Mr. Sherman:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified certain promotional activities by ALZA Corporation (ALZA) that are in violation of the Federal Food, Drug, and Cosmetic Act (Act). Specifically, ALZA promoted its drug, Doxil, as safe or effective for an unapproved indication and made unsubstantiated comparative claims at its promotional exhibit booth at the 36th Annual American Society of Clinical Oncology (ASCO) Meeting in New Orleans.

Doxil is indicated for the treatment of metastatic carcinoma of the ovary in patients with disease that is refractory to both paclitaxel- and platinum-based chemotherapy regimens. Doxil is under accelerated approval and has not yet demonstrated clinical benefit for this indication. Hycamtin (topotecan HCl) is indicated for metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy (i.e., in platinum-sensitive patients).

At your exhibit booth on May 21, 2000, one of your representatives explained to visitors that Doxil has decreased toxicity, specifically, less myelosuppression, than Hycamtin. Your representative further explained that Doxil "targets the tumor, not normal blood cells" and stated that Doxil has comparative efficacy to Hycamtin in ovarian cancer. Such safety and efficacy claims are unsubstantiated and in violation of the Act.

In order to address these objections, DDMAC recommends that ALZA take the following actions:

1. This ALZA representative, and any other ALZA representative or agent, should immediately cease making such violative oral statements and should cease the distribution and use of any Doxil promotional materials that contain the same or similar violative statements.

2. Provide to DDMAC, in writing, your intent to comply with #1 above. Your response should be received by June 21, 2000.

3. This response should describe your method of discontinuing such oral or written statements and should include a list of all similarly violative promotional materials that were discontinued.

If you have any questions, please contact me by facsimile at (301) 594-6771, or by written communication at the Food and Drug Administration; Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID# 9041 and NDA 50-718.

Sincerely,

/S/

Jean-Ah Choi, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications