DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Mr. Stephen Sherman
Director, Labeling and Advertising
Regulatory Affairs
Alza Corporation
1900 Charleston Road
PO Box 7210
Mountain View, CA 94039-7210

RE: NDA # 50-718
Doxil® (doxorubicin HCl liposome injection)
MACMIS ID# 10140

Dear Mr. Sherman:

This letter notifies Alza Corporation (Alza) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified promotional activities that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, Alza made false or misleading claims regarding the safety of Doxil in the commercial exhibit hall of the 37th American Society of Clinical Oncology (ASCO) Annual Meeting held in San Francisco, California in May 2001.

False or Misleading Risk Claims

In the commercial exhibit booth, an Alza representative disseminated a hairbrush[1] and explained to visitors that "We are giving this to you because you don't lose your hair with Doxil." This claim is false or misleading since the approved product labeling (PI) states that alopecia occurs in approximately 15% of the ovarian cancer patients and approximately 9% of the Kaposi's sarcoma patients using Doxil.

Promotional statements or materials are false, lacking in fair balance, or otherwise misleading when they contain representations or suggestions that a drug is safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence. Therefore, the claim that patients don't lose their hair violates the Act because it suggests that Doxil is safer than has been demonstrated.

[1] The hairbrush was labeled Doxil (doxorubicin HCl liposome injection) and was disseminated in conjunction with the approved product labeling.

Requested Actions

Alza should immediately cease making such violative statements and should cease the distribution or use of any promotional materials for Doxil that contain the same or similar violative statements. Alza should submit a written response to DDMAC on or before July 13, 2001, describing its intent and plans to comply with the above. In its letter to DDMAC, Alza should include the date on which this and other similarly violative materials were discontinued.

Alza should direct its response to me by facsimile at (301) 594-6771 or by written communication at the Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 10140 in addition to the NDA number. DDMAC reminds Alza that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joseph A. Grillo, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joseph Grillo
6/28/01 11:26:17 AM