DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Pearl Amos
Associate Director, Regulatory Affairs
SkyePharma
10450 Science Center Drive
San Diego, California 92121

RE: NDA # 21-041
DepoCyt® (cytarabine liposome injection)
MACMIS ID# 10200

Dear Ms. Amos:

This letter notifies SkyePharma 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, SkyePharma's distributor Chiron Corporation (Chiron) promoted DepoCyt for the unapproved use of treating solid tumors in the commercial exhibit hall booth at the 37th American Society of Clinical Oncology (ASCO) Annual Meeting held in San Francisco, California in May 2001.

Promotion of Unapproved Use

At the ASCO Annual Meeting, a Chiron representative told a visitor, "we can send you information about the use of DepoCyt in solid tumors." The representative then swiped the visitor's name badge in order to have information regarding this unapproved use sent by mail. The visitor then received mailed information about DepoCyt that included information about the unapproved use in solid tumor neoplastic meningitis. The information came with a cover letter, which stated "Thank you for your interest and request for information regarding DepoCyt." Thus, the representative's statement and activities show that SkyePharma and its distributor Chiron intended for DepoCyt to be used for unapproved uses.

DepoCyt is indicated for the intrathecal treatment of lymphomatous meningitis. This indication is based on demonstration of increased complete response rate compared to unencapsulated cytarabine. There are no controlled trials that demonstrate a clinical benefit resulting from this treatment, such as improvement in disease-related symptoms, or increased time to disease progression, or increased survival. SkyePharma has not demonstrated that DepoCyt is safe or effective for any other uses at this time.

Requested Actions

SkyePharma and its distributor Chiron should immediately cease making such violative statements and any other promotional activities or materials for DepoCyt that make the same or similar claims or presentations. SkyePharma should submit a written response to DDMAC on or before August 9, 2001, describing its intent and plans to comply with the above. In its letter to DDMAC, SkyePharma should include the date on which this and other similarly violative materials were discontinued.

SkyePharma 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 # 10200 in addition to the NDA number. DDMAC reminds SkyePharma 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
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