DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-041/S008, S010

SkyePharma Inc.
10450 Science Center Drive
San Diego, CA 92121

Attention: Gordon Schooley, Ph.D.
Senior Vice President
Global Clinical and Regulatory Affairs

Dear Dr. Schooley:

Please refer to your supplemental new drug application(s) dated March 31, 2003 (S008) and September 9, 2003 (S010), received April 1, 2003 and September 10, 2003 respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DepoCyt (cytarabine liposome injection).

We acknowledge receipt of your submission dated June 1, 1999 which included final printed labeling which has now been superseded. We will retain this submission in your files.

These "Changes Being Effected" supplemental new drug applications provide for:

S008 change in labeler and secondary package for (b DepoCyt

S010 additions to WARNINGS section regarding central nervous system toxicity

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the submitted labeling text and with the minor editorial revisions indicated below.

1. The final printed labeling (FPL) should combine the changes for S008 and those in S010.

2. An additional reference should be added and the referenced areas revised accordingly:

   ONC Clinical Practice Committee. Cancer Chemotherapy Guidelines and Recommendations for Practice, Pittsburgh, PA: Oncology Nursing Society; 1999:32-41.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted March 31 and September 9, 2003, immediate container and carton labels submitted March 31, 2003). These revisions are terms of the approval of this/these application(s).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL

as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 21-041/S008, S010. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Nicholette Heminway, Regulatory Project Manager, at (301) 594-5750.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Richard Pazdur

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