DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-045/S-021

Pfizer Incorporated
Regulatory Affairs
235 East 42nd Street 150/7/5
New York, NY 10017

Attention: Mr. Alan Traettion
Director of Worldwide Regulatory Affairs

Dear Mr. Traettion:

Please refer to your supplemental new drug application dated April 25, 2003, received April 28, 2003, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emcyt® (estramustine phosphate sodium) Capsules.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PRECAUTIONS section to include the following statement regarding hypocalcemia:

> "Patients with prostate cancer and osteoblastic metastases are at risk for hypocalcemia and should have calcium levels closely monitored."

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted with S-021 on April 25, 2003).

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 supplement NDA 18-045/S-021." 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 Brenda Atkins, Regulatory Project Manager, at (301) 594-5767.

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

Enclosure: Labeling – 4 pages

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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