DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-045/S023

Pfizer Global Pharmaceuticals
Attention: Mary Boylan-Bost
Associate Director
Worldwide Regulatory Strategy
235 East 42nd Street, 605/5/54
New York, NY 10017-7555

Dear Ms. Boylan-Bost:

Please refer to your supplemental new drug application S023 dated and received July 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMCYT® (estramustine phosphate sodium) 140 milligram tablets.

We acknowledge receipt of your submission dated July 31, 2007.

This "Changes Being Effected" supplemental new drug application provides for:

Labeling revision of the display panel of the carton and container as requested by the FDA letter dated March 28, 2007 to include the following text in red color ink:

Store in refrigerator at 36° to 46° (2° to 8° C)

Labeling revision of the package insert in the HOW SUPPLIED-NOTES section with the following text:

EMCYT Capsules should be stored in the refrigerator at 36° to 46°F (2° to 8°C).

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

The final printed labeling (FPL) must be identical to the enclosed labeling and/or submitted labeling (package insert) submitted July 31, 2007.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated July 31, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 18-045/S023".

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Brenda Atkins, Regulatory Project Manager, at (301) 796-2330.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Robert Justice

7/9/2008 07:05:47 PM