DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-778/S-008

Pfizer Inc.
235 E. 42nd Street
New York City, NY 10017

Attention: Kristina D. Spranger
Senior Manager, US Regulatory Affairs

Dear Ms. Spranger:

Please refer to your supplemental new drug application dated April 30, 2004, received May 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for for ELLENCE® (epirubicin hydrochloride injection) 50mg/25mL and 200mg/100mL single-use vials.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 14, December 22, 2004 and February 7, 2005, February 16, and February 24, 2005. We also acknowledge and retain your final printed labeling submitted August 29, 2003.

This supplemental new drug application provides for labeling revisions updating the Black Box **WARNING**, **CLINICAL STUDIES**, **WARNINGS**, and **ADVERSE REACTIONS** sections to include additional follow-up data from studies MA-5 and GFEA-05.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-778/S-008**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure - Labeling

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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