DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050778/S-015/S-017/S-018

SUPPLEMENT APPROVAL

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

Attention: Beatrice Curran
Associate Director, Worldwide Regulatory Strategy

Dear Ms. Curran:

Please refer to your Supplemental New Drug Applications (sNDA) dated October 29, 2007, November 4, 2009, and June 30, 2010, received October 29, 2007, November 4, 2009, and June 30, 2010, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ellence® (epirubicin hydrochloride injection).

We acknowledge receipt of your amendments dated November 2, December 1 and December 23, 2010.

"Changes Being Effected" labeling supplement 015 provides for updates to the Drug-Drug Interactions, Precautions and How Supplied sections of the package insert as a result of the update of Pfizer's Core Data Sheet. In addition, this supplement provides for label harmonization changes and editorial changes.

"Changes Being Effected" labeling supplement 017 provides for revisions to the Warnings, Precautions, and Dosage and Administration sections of the package insert to incorporate information related to cardiotoxicity relative to dosing with other cardiotoxic drugs and risk of infection following vaccination.

"Prior Approval" labeling supplement 018 provides for conversion of the labeling to PLR format.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below which have already been incorporated into the enclosed labeling.

1. Update the Recent Major Changes section of Highlights to reflect content revisions in the Dosage and Administration, Warnings and Precautions, and Drug Interactions sections of the Full Prescribing Information.

2. Update the Table of Contents to reflect current placement and titles of sections.

3. Update the Full Prescribing Information to include left margin marks identifying recent changes.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPLR files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Christy Cottrell, Regulatory Project Manager, at (301) 796-4256.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AMNA IBRAHIM
09/14/2011