DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050778/S-019

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Shai Srulovich
East 42nd Street
New York, NY 10017

Dear Mr. Srulovich:

Please refer to your Supplemental New Drug Application (sNDA) dated May 2, 2012, received May 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ellence (epirubicin hydrochloride) for Injection.

We acknowledge receipt of your amendments dated June 11, July 18, September 28, October 19, and November 16, 2012.

This "Changes Being Effected" supplemental new drug application provides for proposed revisions to the package inert:

1) Revision of "severe myocardial insufficiency" to "cardiomyopathy and/or heart failure" in Highlights and Section 4, Contraindications
2) Revision of Section 5.12, Pregnancy to add "Women of child-bearing potential should be advised to avoid becoming pregnant during treatment and should use effective contraceptive methods *[see Use In Specific Populations (8.1)]*."
3) Revised Section 6.2, Overview of Acute and Delayed Toxicities to add "Other serious drug-related cardiovascular adverse events that occurred during clinical trials with ELLENCE, administered in different indications, include ventricular tachycardia, AV block, bundle branch block, bradycardia and thromboembolism."
4) Added a new Section 6.3 Adverse Reactions Identified During Post-Approval Use.

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

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 SPL 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 that includes labeling changes 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Alice Kacuba, Chief, Project Management Staff, at (301) 796-6412.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology 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
02/19/2013