DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022234/S-011
NDA 202356/S-003

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Erin Wierzbicki, MS
Senior Associate
Pfizer Essential Health Global Regulatory Affairs
275 North Field Drive Bldg 111
Lake Forest, IL 60045

Dear Ms. Wierzbicki:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 21, 2018, received February 21, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Docetaxel Injection 10 mg/mL and 20 mg/mL (NDA 022234/S-011), and Docetaxel Injection Concentrate, 10 mg/mL sterile parenteral solution, 10 mg, 80 mg, 130 mg, 200 mg vials (NDA 202356/S-003).

These Prior Approval supplemental new drug applications propose the addition of new safety information to the following sections of the labeling:

- WARNINGS AND PRECAUTIONS (5.4) – Addition of a warning statement on the possible risk of developing a hypersensitivity reaction to docetaxel, including a more severe hypersensitivity reaction, in patients who have previously experienced a hypersensitivity reaction to paclitaxel.

- ADVERSE REACTIONS (6.2) – Addition of hypersensitivity reactions reported with docetaxel in patients who previously experienced hypersensitivity reactions to paclitaxel; addition of injection site recall reaction.

- PATIENT INFORMATION – Patient-friendly language has been added to align with the proposed safety updates to the WARNINGS AND PRECAUTIONS (5.4) and ADVERSE REACTIONS (6.2) as described above.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 prescribing information and the patient 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 include 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Amy Tilley Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

AMNA IBRAHIM
09/24/2018