DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020449/S-079

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
Attention: Stefanie Doty
Director, Regulatory Affairs
55 Corporate Drive, Mail Stop: 55C-300
Bridgewater, NJ 08807

Dear Ms. Doty:

Please refer to your Supplemental New Drug Application (sNDA) dated April 11, 2018, received April 11, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Taxotere® (docetaxel) Injection Concentrate, 20 mg/mL and 80 mg/4 mL.

This Prior Approval supplemental new drug application provides for the addition of "Enterocolitis and Neutropenic Colitis" and for updates to "Hypersensitivity Reactions" in Section 5 "Warnings and Precautions" of the Prescribing Information (PI). Also, this Supplemental NDA provides for updates to Sections 6 "Adverse Reactions", 6.2 "Postmarketing Experience", and 17 "Patient Counseling" of the PI to reflect the above changes in Section 5 and to distinguish between risk of adverse events (AEs) during the TAX316 adjuvant breast cancer study and AEs persistent following completion of the trial, with a median follow-up time of 8 years, with regard to the following AEs: peripheral neuropathy, alopecia, amenorrhea, peripheral edema, lymphedema, asthenia, and myelodysplastic syndrome/acute myeloid leukemia (MDS/AML).

APPROVAL & LABELING

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 and text for 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 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).

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 Sakar Wahby, Regulatory Project Manager, at (240) 402-5364 or email me at sakar.wahby@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Supervisory Associate Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

LALEH AMIRI KORDESTANI
10/05/2018