DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020449/S-071

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
Attention: Fran Polizzano, Pharm.D.
Sr. Manager, U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Dr. Polizzano:

Please refer to your Supplemental New Drug Application (sNDA) dated June 19, 2013, received June 19, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Taxotere® (docetaxel) Injection Concentrate; 20 mg and 80 mg.

We acknowledge receipt of your amendments dated June 20, 2013; October 24, 2013; and November 19, 2013.

This "Prior Approval" supplemental new drug application provides for revisions to:

PRESCRIBING INFORMATION

- Addition to the WARNINGS AND PRECAUTIONS SECTION of the highlights:

  Eye disorders: Cystoid macular edema (CME) has been reported and (b) (4) treatment discontinuation. (5.9)

- Addition of a new WARNINGS AND PRECAUTIONS section:

  5.9 Eye Disorders

  Cystoid macular edema (CME) has been reported in patients treated with TAXOTERE, (b) (4). Patients with impaired vision should undergo a prompt and (b) (4) ophthalmologic examination. If CME is diagnosed, TAXOTERE treatment should be discontinued and appropriate treatment initiated. Alternative non-taxane cancer treatment should be considered.

- Addition of the sentence "Cases of cystoid macular edema (CME) have been reported in patients treated with TAXOTERE, (b) (4)." to the ADVERSE REACTIONS, Postmarketing Experiences, Opthalmologic section of the package insert.

- Addition of a new section to ADVERSE REACTIONS, Postmarketing Experiences:

  Metabolism and nutrition disorders: cases of hyponatremia have been reported, (b) (4).

PATIENT INFORMATION

- Addition to the "**What are the possible side effects of TAXOTERE?**" section:

(b) (4)

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, text for the patient package insert, Medication Guide), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Modupe Fagbami, Regulatory Project Manager, at (301) 796-1348.

Sincerely,

{See appended electronic signature page}

Anthony J. Murgo, M.D., M.S.
Acting Director, Division of Oncology Products 1
Associate Office Director for Regulatory Science
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/

ANTHONY J MURGO
12/13/2013