DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020449/S-043 **SUPPLEMENT APPROVAL**

sanofi-aventis U.S. LLC
Attention: Gina L. Vestea, PharmD.
Senior Manager, US Regulatory Affairs Marketed Products
Mailstop: 55A-430A
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807-5925

Dear Dr. Vestea:

Please refer to your Supplemental New Drug Application (sNDA) dated December 19, 2006, received December 20, 2006, 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 submission dated April 16, 2010.

This "Changes Being Effected 30 Days" supplemental new drug application provides for changes to the carton, immediate container, film and diluent labels.

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.

Submit final printed carton, immediate container, film and diluent labels that are identical to the enclosed carton, immediate container, film and diluent labels and carton, immediate container, labels submitted on April 16, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton, Immediate Container, Film and Diluent Labels for Approved NDA020449/S-043."** Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Carton and Container Labeling
Film Labeling
Diluent Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20449	SUPPL-43	SANOFI AVENTIS US LLC	TAXOTERE

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
06/03/2010
For Dr Robert Justice