



NDA 020449/S-044
NDA 020449/S-053

SUPPLEMENT APPROVAL

Linda Gustavson, Ph.D., RAC
Director, R & D Regulatory Affairs
U.S. Head, Oncology
Global Regulatory Affairs
sanofi-aventis US Inc.
Mail code: BX2-712B
200 Crossing Blvd, Bridgewater, NJ 08890-0890

Dear Dr. Gustavson:

Please refer to your March 13, 2007, supplemental New Drug Application, received March 14, 2007, and to your November 12, 2008, supplemental New Drug Application, received November 13, 2008, 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 submissions dated November 21, 2008; February 13, June 15 (2), and October 13, 2009; January 20(2), and April 6(2), 2010.

The S-044 "Changes Being Effectuated" supplemental New Drug Application provides for revisions to the Warnings, Adverse Reactions, and Postmarketing Experience sections of the package insert.

The S-053 "Changes Being Effectuated" supplemental New Drug Application provides for revisions to the Postmarketing Surveillance Information and Drug Interactions sections of the label.

Your June 15, 2009, amendments to S-044 and S-053, also provide for revisions to the Dosage and Administration and Dosage Forms and Strengths sections of the package insert.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 020449/S-044 and S-053.

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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) 793-1348.

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

Enclosures:

Package Insert

Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20449	SUPPL-53	SANOFI AVENTIS US LLC	TAXOTERE
NDA-20449	SUPPL-44	SANOFI AVENTIS US LLC	TAXOTERE

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/s/

ROBERT L JUSTICE
04/20/2010