DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-449/S-039

Eric Phillips, M.S., Sc.D.
Associate Director, Oncology Products
Corporate Regulatory Affairs
Sanofi-aventis U.S. Inc.
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated April 14, 2006, received April 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAXOTERE® (docetaxel) Injection Concentrate, 20 mg and 80 mg.

We acknowledge receipt of your submissions dated April 14; May 30; June 8, 15, 16, and 21; July 6, and 11; August 11; and September 13 (e-mail), 16 (e-mail), and 17 (e-mail), 2006.

This supplemental new drug application provides for the use of TAXOTERE® (docetaxel) Injection Concentrate in combination with cisplatin and fluorouracil for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-449/S-039.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submissions dated November 21, 1995, (Original NDA) and August 18, 2004 (S-029). These commitments are listed below.

COMMITMENT 5 (Original NDA):

Ongoing and future studies in patients with elevated bilirubin or patients with combined elevations of transaminase and alkaline phosphatase to define safe and effective doses in such patients. Such studies should include pharmacokinetic evaluation in addition to assessment of efficacy and safety.

COMMITMENT 1 (S-029):

To submit a complete report of the updated TAX 316 data to verify the efficacy based on 700 events of DFS and safety of Taxotere in the adjuvant treatment of women with operable node-positive breast cancer and to submit final analysis of overall survival (expected to occur in the year 2010).

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."

Promotional materials should be submitted, in duplicate, directly 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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Frank H. Cross, Jr., Chief Project Management Staff, at (301) 796-0876.

Sincerely,

{See appended electronic signature page}

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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Justice

10/17/2006 01:52:04 PM