



**NDA 20-449/S-045**

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 March 29, 2007, received March 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAXOTERE® (docetaxel) Injection Concentrate, 20 mg and 80mg.

We acknowledge receipt of your submissions dated May 11 and 22, June 29, July 27, August 17, September 14, 18, and 26 (electronic), 2007.

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 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) for this supplement S-045 must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Please note that your final printed labeling submitted December 19, 2006, for S-039 has been superseded but will be retained in the file.

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-045.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated August 18, 2004 (S-029). This commitment is listed below.

**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 the 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).

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If you have any questions, please call Frank Cross, Jr., Regulatory Project Manager, at (301) 796-0876.

Sincerely,

*{See appended electronic signature page}*

Ramzi Dagher, M.D.  
Deputy Division Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Ramzi Dagher  
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