DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-492/S-006
NDA 21-759/S-001

Sanofi-aventis U.S. LLC.
300 Somerset Corporate Blvd.
P.O. Box 6977
Bridgewater, NJ 08807-0977

Attention: MaryRose A. Salvacion
Senior Manager, US Regulatory Affairs Marketed Products

Dear Ms. Salvacion:

Please refer to your supplemental new drug applications dated July 13, 2005, received July 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ELOXATIN® (oxaliplatin for injection) and ELOXATIN® (oxaliplatin injection).

These supplemental new drug applications provide for revisions to the patient package insert.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. The **What is ELOXATIN?** section should be revised as follows to ease readability for a broader range of patients with different educational backgrounds:

   "ELOXATIN (eh-LOX-ah-tin) is an anticancer (chemotherapy) medicine that is used:
   - to treat adults with stage III colon cancer after surgery to remove the tumor.
   - with other anti-cancer medicines called 5-fluorouracil (5-FU) and leucovorin (LV) to treat adults with advanced colon or rectal cancer (colo-rectal cancer).

   ELOXATIN with infusional 5-FU and LV was shown to lower the chance of colon cancer returning when given to patients with stage III colon cancer after surgery to remove the tumor. It is not known if ELOXATIN increases survival in patients with stage III colon cancer. ELOXATIN with infusional 5-FU and LV was also shown to increase survival, shrink tumors and delay growth of tumors in some patients with advanced colorectal cancer."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the patient package insert). These revisions are terms of the approval of these applications.

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 these submissions "**FPL for approved supplement NDA 21-492/S-006 and NDA 21-759/S-001**." Approval of these submissions 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 these applications.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Drug Oncology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
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 these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Christy Cottrell, Consumer Safety Officer, at (301) 796-1347.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting 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

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