DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-492/S-011
NDA 21-759/S-009

sanofi-aventis U.S.
Attention: Laura Cooper
Senior Manager, US Regulatory Affairs Marketed Products
55 Corporate Drive
P.O. Box 5925
Bridgewater, NJ 08807-5925

Dear Ms. Cooper:

Please refer to your supplemental new drug applications dated July 25, 2008, received July 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eloxatin (oxaliplatin) powder for solution for intravenous use and Eloxatin (oxaliplatin) concentrate for solution for intravenous use.

We acknowledge receipt of your submissions dated January 9, 23 and 26, February 17, and 24, 2009 (electronic).

These supplemental new drug applications provide for the following additions.

- to section 6.2 Postmarketing Experience:
  "sometimes fatal" was added after "other interstitial lung diseases"
  "and transient vision loss (reversible following therapy discontinuation)"

- to section 17.1 Information for Patients:
  Updated with text regarding vision abnormalities that may affect patients' ability to drive and use machines.

- to section 10 OVERDOSAGE:
  Description of first five cases has been removed; a list of main expected events and main events observed in overdose cases has been provided, updated with events observed with new overdose cases. In addition, the maximum single dose of Eloxatin administered was added.

- to section 8.5 Geriatric Use:
  Updated with safety data from the adjuvant setting, based on the Final Study Report of MOSAIC-EF3313 submitted on October 31, 2007.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the 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)] 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 pharmacist information sheet, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 21-492/S-011"** and **"SPL for approved NDA 21-759/S-009"**.

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

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
Suite 12B05
5600 Fishers Lane
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 Lisa Skarupa, Regulatory Project Manager, at (301) 796-2219.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Division Director
Division of Drug Oncology 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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