DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-492/S-010
NDA 21-759/S-008

Brenda W. Kozan
Assistant Director, Regulatory Development
Corporate Regulatory Affairs
sanofi-aventis U.S. Inc.
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Kozan:

Please refer to your supplemental new drug applications dated November 21, 2007, received November 21, 2007, 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 May 7 and 21 (electronic), 2008.

NDA 21-492/S-010 and NDA 21-759/S-008 provide combined labeling in PLR format which includes the final overall survival data and updated disease-free survival data from the MOSAIC study, EFC3313, oxaliplatin in combination with 5-Fluorouracil (5-FU) and leucovorin (LV) for the adjuvant treatment of patients with stage II or III (Dukes' B2/C) colon cancer.

We have 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 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-010 and NDA 21-759/S-008."

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

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 supplements NDA 21-492/S-010 and NDA 21-759/S-008**." 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.

Regarding your postmarketing study commitment #1 in your submission dated November 4, 2004, for NDA 21-492/S004 and S005:

All patients in the MOSAIC trial (EFC3313) should be followed for efficacy until death or for at least 6 years with submission of study reports annually and a final study report submitted by the 3rd quarter of 2007.

This commitment is fulfilled.

We remind you of your postmarketing study commitments in your submission dated August 9, 2002 for NDA 21-492. These commitments are listed below.

COMMITMENT #7:

Design and conduct a study (POP5347) to examine the safety of administering repeated doses of oxaliplatin 85 mg/m2 in combination with infusional 5-FU/LV, at the doses and schedule recommended in the product label, in patients with varying degrees of renal impairment. This study should include patients with normal renal function, minimally impaired renal function, and moderately impaired renal function. The study should be designed to assess whether there are differences in safety between each of the different subgroups of renal impairment compared to a control group with normal renal function. Differences in proportions of patients with all grades and grade 3/4 gastrointestinal, neurological, renal and hematological toxicities, differences in time to onset and duration of grade 3/4 neurotoxicity, and differences in proportions of patients who require dose reductions should be evaluated. A subgroup of patients with severe renal toxicity should also be considered for study, possibly at a lower starting dose.

COMMITMENT #8:

Submit reports of all medication errors, both potential and actual, that occur within the United States with oxaliplatin for two years following the date of approval. Potential errors should be reported and summarized quarterly. All actual errors should be submitted within 15 days regardless of patient outcome. Yearly reports of potential and actual errors occurring with oxaliplatin should be submitted for two years following the date of approval.

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 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 www.fda.gov/cder/ddmac.

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/

Ramzi Dagher
5/21/2008 06:00:44 PM
Signing for Dr. Robert Justice, Division Director, DDOP