



NDA 21492/S-012 and 21759/ S-012

SUPPLEMENT APPROVAL

sanofi-aventis, U.S. LLC
Attention: Manfred H. Fleshcar, Ph.D., MS, RAC
US Regulatory Affairs Marketed Products
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807-0890

Dear Dr. Fleshcar:

Please refer to your Supplemental New Drug Application (sNDA) dated May 13, 2010, received May 13, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eloxatin® (oxaliplatin) powder for intravenous use. We also refer to your Supplemental New Drug Application (sNDA) dated May 14, 2010, received May 14, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Eloxatin® (oxaliplatin) concentrate for solution for intravenous use.

This “Prior Approval” supplemental new drug application proposes additions based on post-marketing surveillance: addition of renal disorders to sections Highlights, Dosage and Administration, Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology and addition of Reversible Posterior Leukoencephalopathy Syndrome to sections Warnings and Precautions, and Adverse Reactions.

We also refer to your submission received April 12, 2011, your emails dated October 25, 2011 and November 10, 2011, and your submission dated December 13, 2011.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

In HIGHLIGHTS, under RECENT MAJOR CHANGES, we removed the brackets, changed the subheadings to section headings, and deleted the reference to the Pediatric Use subsection. We refer you to 21 CFR 201.57(a)(5).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content

of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

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 L. Justice, M.D., M.S.
Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

ROBERT L JUSTICE
12/28/2011