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APPLICATION NUMBER:

ANDA 078817Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078817

Sandoz Inc.
Attention: Bernadette Attinger
Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 8, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxaliplatin Injection USP, 5 mg/mL, (Preservative-Free), packaged in 50 mg/10 mL, 100 mg/20 mL, and 200 mg/40 mL Single-use Vials.

Reference is also made to the tentative approval letter issued by this office on August 3, 2009, and to your amendments dated April 23, June 28, July 23, September 30, October 29, and November 12, 2010. In addition, we acknowledge receipt of your correspondences dated June 28, and September 13, 2010, addressing the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, your Oxaliplatin Injection USP, 5 mg/mL, (Preservative-Free), packaged in 50 mg/10 mL, and 100 mg /20 mL Single-use Vials is approved, effective on the date of this letter. However, because of the 180-day generic drug exclusivity issue explained below, we are unable to grant final approval to your Oxaliplatin Injection USP, 5 mg/mL (Preservative-Free), packaged in 200 mg/40 mL Single-use Vials. Your Oxaliplatin Injection USP, 5 mg/mL, (Preservative-Free), packaged in 200 mg/40 mL single-use vials, remains tentatively approved and will not be eligible for final approval until the 180-day generic drug exclusivity period associated with this strength has been resolved.

The reference listed drug (RLD) upon which you have based your ANDA, Eloxatin Injection, of Sanofi Aventis US, LLC (Sanofi), is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,290,961 (the '961 patent)	July 12, 2013
5,338,874 (the '874 patent)	October 7, 2013
5,420,319 (the '319 patent)	February 9, 2017
5,716,988 (the '988 patent)	February 7, 2016

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Oxaliplatin Injection USP, 5 mg/mL, packaged in 50 mg/10 mL, 100 mg /20 mL, and 200 mg/40 mL Single-use Vials, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Sandoz Inc. (Sandoz) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Sandoz complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '874 and '988 patents was brought against Sandoz within the statutory 45-day period in the United States District Court for the District of New Jersey [Sanofi-Aventis U.S. LLC v. Sandoz Inc., Civil Action Nos. 3:08-CV-02693-FLW-JJH and 07-CV-02762]. You have also notified the agency that on April 14, 2010, a Consent Judgment was issued and there was an agreement between Sandoz and Sanofi-Aventis U.S. LLC. Therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

I. Approval of Oxaliplatin Injection USP, 5 mg/mL, packaged in 50 mg/10 mL and 100 mg/20 mL Single-use Vials

The Division of Bioequivalence has determined your Oxaliplatin Injection USP, 5 mg/mL, packaged in 50 mg/10 mL and 100 mg/20 mL Single-use Vials to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Eloxatin Injection, 5 mg/mL, packaged in 50 mg/10 mL and 100 mg/20 mL Single-use Vials, respectively.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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/U_CM072392.pdf The SPL will be accessible via publicly available labeling repositories.

II. Tentative Approval of Oxaliplatin Injection USP, 5 mg/mL, packaged in 200 mg/40 mL Single-use Vials.

We are unable at this time to grant final approval to your Oxaliplatin Injection USP, 5 mg/mL, packaged in 200 mg/40 mL Single-use Vials because another ANDA for Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials, containing a paragraph IV certification was received by this office prior to the receipt of your application for this strength. This other ANDA, therefore, is eligible for 180-day generic drug exclusivity for Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials. Accordingly, your ANDA will be eligible for final approval 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act.

Our decision to tentatively approve your Oxaliplatin Injection, 5 mg/mL, packaged in 200 mg/40 mL Single-dose Vials, is based upon information currently available to the agency, i.e., data in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product. This decision is subject to change on the basis of new information that may come to our attention.

To reactivate your ANDA prior to final approval of the 200 mg/40 mL strength, please submit a "***MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED***"" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "***MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED***"

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional supplements, please contact Esther Chuh, Pharm.D., Project Manager, at 240-276-8530.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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 WEST

01/24/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.