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APPLICATION NUMBER:
ANDA 090849Orig1s000

APPROVAL LETTER



ANDA 090849

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 September 22, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxaliplatin for Injection USP, 50 mg/vial and 100 mg/vial Single-dose Vials.

Reference is also made to your amendments dated December 10, 2008; March 2, July 28, September 10, and September 21, 2009; January 12, April 29, June 18, and July 7, 2010; and January 5, March 4, March 29, and April 13, 2011. In addition, we acknowledge receipt of your correspondences dated November 11, November 21, and December 30, 2008; and January 27, February 10, and September 30, 2009, 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 ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Oxaliplatin for Injection USP, 50 mg/vial and 100 mg/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Eloxatin for Injection, 50 mg/vial and 100 mg/vial, of Sanofi Aventis US, LLC (Sanofi).

The RLD upon which you have based your ANDA, Sanofi's Eloxatin for Injection, 50 mg/vial and 100 mg/vial, 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"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
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

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 for Injection USP, 50 mg/vial and 100 mg/vial, under this ANDA. You have notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '874 patent 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. EBEWE Pharma Ges.m.b.H.Nfg.KG, Civil Action No. 3:07-CV-03164-FLW-JJH]. This action was then consolidated with Civil Action 07-cv-2762 in the District of New Jersey. You have also notified the agency that on July 9, 2009, the district court entered a consent judgment and order ending the litigation; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

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/UCM072392.pdf> The SPL will be accessible via publicly available labeling repositories.

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

04/28/2011

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