DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78803

Actavis Totowa LLC
Attention: Joanne Stavole
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 9, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxaliplatin for Injection USP, (Preservative-Free), packaged in 50 mg and 100 mg Single-dose Vials.

Reference is also made to the tentative approval letter issued by this office on January 15, 2010, and to your amendments dated April 1, and November 22, 2011; and May 3, July 11, and July 26, 2012. In addition, we acknowledge receipt of your correspondence dated April 1, 2011; and July 24, 2012, addressing patent issues associated with this ANDA.

We note that the reference listed drug (RLD) upon which you have based this ANDA, Eloxatin for Injection (Lyophilized), 50 mg and 100 mg/vial of Sanofi Aventis US, LLC, is no longer being marketed in the U.S. and is currently listed in the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". Reference is made to the Federal Register notice (Volume 72, No. 226) in which the agency announced its determination that Eloxatin for Injection (Lyophilized) was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

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, the ANDA is approved, effective on the date of this letter. The Division of

Bioequivalence has determined your Oxaliplatin for Injection USP, 50 mg and 100 mg packaged in Single-dose Vials, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Eloxatin for Injection, 50 mg and 100 mg, respectively, packaged in Single-dose Vials, 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 their 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

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents 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 Actavis Totowa, LLC (Actavis) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '874 patent was brought against Actavis within the statutory 45-day period in the United States District Court for the District of New Jersey [Sanofi-Aventis U.S. LLC v. Actavis Totowa LLC, Civil Action No. 3:07-CV-3142-FLW-JJH]. You have also notified the agency that the case has been dismissed.

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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion 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}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
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
08/08/2012
Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.