DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077983

TEVA Parenteral Medicines, Inc.
Attention: Deborah A. Jaskot
VP, N. American Regulatory
Affairs Policy & Governance
19 Hughes
Irvine, CA 92618

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 10, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Gemcitabine for Injection USP, 200 mg/vial and 1 gram/vial, Single-use Vials.

Reference is also made to the letter rescinding approval issued by this office on August 31, 2010, and to your amendments dated December 22, 2010; January 6 (2 submissions), January 13, January 17, and January 21 (2 submissions), 2011.

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 Gemcitabine for Injection USP, 200 mg/vial and 1 gram/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Gemzar for Injection, 200 mg/vial and 1 gram/vial, of Eli Lilly and Co. (Lilly).

The RLD upon which you have based your ANDA, Lilly's Gemzar for Injection, 200 mg/vial and 1 gram/vial, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,464,826 (the '826 patent) is scheduled to expire (with pediatric exclusivity added) on May 7, 2013.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '826 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Gemcitabine for Injection USP, 200 mg/vial and 1 gram/vial, under this ANDA. You have notified the agency that TEVA Parenteral Medicines, Inc. (TEVA Parenteral) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '826 patent was initiated against TEVA Parenteral within the statutory 45-day period in the United States District Court for the Southern District of Indiana, Indianapolis Division [Eli Lilly and Company v. SICOR Pharmaceuticals, Inc., SICOR, Inc., TEVA Pharmaceutical Industries USA, Inc., Civil Action No. 1:06-cv-0238-SEB-VSS]. The 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired. Were are also aware, in a case involving a different ANDA applicant, of the issuance of a mandate from the United States Court of Appeals for the Federal Circuit in which the court affirmed a prior decision that the '826 patent is invalid.

With respect to 180-day generic drug exclusivity, we note that TEVA Parenteral was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '826 patent. Therefore, with this approval, TEVA Parenteral is eligible for 180-days of generic drug exclusivity for Gemcitabine for Injection USP, 200 mg/vial and 1 gram/vial, Single-use Vials. This exclusivity which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

We 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(s) 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.

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

01/25/2011

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