



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 77-983

TEVA Parenteral Medicines, Inc.  
Attention: Susan O'Brien  
Director, Regulatory Affairs  
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, 1 gram/Single-use Vial.

Reference is also made to the tentative approval letter issued by this office on May 16, 2007, and to your amendments dated June 25, September 11, and November 21, 2008.

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, 1 gram/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Gemzar for Injection, 1 gram/vial, of Eli Lilly and Co.

The reference listed drug (RLD) upon which you have based your ANDA, Gemzar for Injection, 1 gram/vial of Eli Lilly and Co. (Eli Lilly), is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,808,614 (the '614 patent) and 5,464,826 (the '826 patent) are scheduled to expire (with pediatric exclusivity added) on November 15, 2010 and May 7, 2013, respectively.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Gemcitabine for Injection USP, 1 gram/vial, 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 TEVA Parenteral Medicines, Inc. (TEVA Parenteral) for infringement of one or both of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against TEVA Parenteral prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that TEVA Parenteral complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against TEVA Parenteral for infringement of the '614 and '826 patents 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]. Although this litigation remains ongoing, 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.

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 '614 and '826 patents. Therefore, with this approval, TEVA Parenteral is eligible for 180-days of generic drug exclusivity for Gemcitabine for Injection USP, 1 gram/vial. 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 505-1(i).

Postmarketing reporting requirements for this ANDA application 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 Amundson 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "**Miscellaneous Correspondence - SPL for Approved ANDA 77-983**".

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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

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Robert L. West  
12/18/2008 10:01:34 AM  
Deputy Director, for Gary Buehler