CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 202063

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202063

Emcure Pharmaceuticals USA Inc.
U.S. Agent for Emcure Pharmaceuticals Ltd.
Attention : Pankaj Dave, Ph.D.
Vice President, Regulatory Affairs
21-B Cotters Lane
East Brunswick, NJ 08816

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 19, 2010, 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 g/vial, packaged in Single-use Vials (Lyophilized).

Reference is also made to your amendments dated December 1, 2010; April 27, June 2, and August 20, 2011; and April 3, and June 13, 2012. In addition, we acknowledge receipt of your correspondence dated June 14, July 5, and August 8, 2012, addressing 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 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 g/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lilly's Gemzar for Injection, 200 mg/vial and 1 g/vial.

The RLD upon which you have based your ANDA, Lilly's Gemzar for Injection, 200 mg/vial and 1 g/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 on May 7, 2013 (with pediatric exclusivity added).

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 g/vial, under this ANDA. You have notified the agency that Emcure Pharmaceuticals Limited (Emcure) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Emcure within the statutory 45-day period.

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}

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/

GREGORY P GEBA
09/11/2012