

**CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**ANDA 200771**

**APPROVAL LETTER**



ANDA 200771

Emcure Pharmaceuticals USA Inc.  
U.S. Agent for Emcure Pharmaceuticals Ltd.  
Attention: Mr. Nilesh Patel  
21/B Cotters Lane  
East Brunswick, NJ 08816

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 1, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Irinotecan Hydrochloride Injection, 20 mg/mL, packaged in 40 mg/2 mL and 100 mg/5 mL Single-dose Vials.

Reference is also made to your amendments dated February 9, June 3, and October 1, 2010; July 8, 2011; and January 25, February 2, 2012.

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 Irinotecan Hydrochloride Injection, 20 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Camptosar Injection, 20 mg/mL, of Pfizer, Inc.

The reference listed drug product (RLD) referenced in your application, Camptosar Injection, of Pfizer, Inc. is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,403,569 (the '569 patent)	October 28, 2020*
6,794,370 (the '370 patent)	November 1, 2020*

\*With Pediatric Exclusivity

With respect to the '569 and '370 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents, and that these patents do not claim any proposed indication for which you are seeking approval under this ANDA.

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(1)] 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

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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

02/14/2012

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