

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208313Orig1s000

PHARMACOLOGY REVIEW(S)



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

NDA #: 208313
Supporting document: 1
Application letter date: 3/29/2015
CDER stamp date: 3/30/2015
Product: Gemcitabine Hydrochloride
Applicant: Sun Pharmaceutical Industries, Ltd.
Review Division: Division of Hematology Oncology Toxicology (DHOT) for
the Division of Oncology Products 2 (DOP2)
Reviewer: Alexander H. Putman, PhD
Supervisor: Whitney S. Helms, PhD
Division Director: John K. Leighton, PhD, DABT (DHOT);
Patricia Keegan, MD (DOP2)

Sun Pharmaceutical Industries Ltd. has submitted a New Drug Application (NDA) for a "ready-to-infuse" formulation of Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection, 10 mg/mL. This NDA has been submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. The proposed indication, dose, route, and duration of administration of Sun Pharmaceutical Industries Ltd. Gemcitabine Hydrochloride in 0.9% Sodium Chloride Injection, 10 mg/mL will be the same as those of the reference drug, Gemzar®, and thus, reliance on the pharmacology/toxicology information required for the approval of this product is based on previous FDA findings for the safety of the listed drug. Sun Pharmaceutical Industries Ltd. has not conducted or sponsored any non-clinical pharmacokinetic or toxicology studies for this NDA, including any non-clinical studies to support changes in the impurity profile compared to the listed drug or the use of novel excipients. Thus, a pharmacology and toxicology review is not warranted and there are no pharmacology/toxicology issues that would impact the acceptability of this application or the approval of this product at this time.

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/s/

ALEXANDER H PUTMAN
10/13/2015

WHITNEY S HELMS
10/14/2015

I concur with the conclusions of Dr. Putman.