CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209604Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

Date: June 29, 2017
From: Stephanie L Aungst, PhD
Pharmacology/Toxicology Reviewer
Division of Hematology Oncology Toxicology for Division of Oncology Products 2
Through: Whitney S. Helms, PhD
Supervisory Pharmacologist
Division of Hematology Oncology Toxicology for Division of Oncology Products 2
To: NDA 209604
Re: Pharmacology and Toxicology

On October 13, 2016 Accord Healthcare Inc., submitted a New Drug Application (NDA) for gemcitabine for injection under the 505(b)(2) pathway, identifying the listed drug as Gemzar® under NDA 020509 held by Eli Lily, approved on May 15, 1996. Gemcitabine is a nucleoside metabolic inhibitor. Accord is relying on the findings described in the label for Gemzar to support the nonclinical requirements for evaluation of gemcitabine, thus no nonclinical studies were submitted to support this NDA. The Applicant based proposed specification limits for (b) (4) (NMT (b) (4) %) and (b) (4) (NMT (b) (4) %) on a dose of (b) (4) mg/m^2 rather than the maximum dose of 1250 mg/m^2 approved for the breast cancer indication. (b) (4)

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The Applicant was asked to lower the specifications to levels based on calculations using the 1250 mg/m^2 as the maximum dose and changed the levels for (b) (4) to NMT (b) (4) % and (b) (4) %, respectively. No new impurities or

(b) (4)

degradants were identified by the CMC review team during the course of the review period that would require additional safety qualification studies in animals. There were no pharmacology/toxicology issues that arose during the review period that would prevent approval of Accord Gemcitabine.

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/s/

STEPHANIE L AUNGST
07/17/2017

WHITNEY S HELMS
07/17/2017

I concur with Dr. Aungst's conclusions that the revised specifications for impurities/solvents are reasonably supported by the available nonclinical safety data and that there are no outstanding issues from a pharmacology/toxicology perspective that would prevent the approval of Gemcitabine for Injection under the 505(b)(2) pathway.