CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210661Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

MEMORANDUM

Date: 2/23/2018

From:	Safaa Burns, Ph.D. (DCP V/OCP)
Through:	Jeanne Fourie Zirkelbach, Ph.D. (DCP V/OCP)
For:	NDA 210661/SDN 1
Product Name:	Pemetrexed for Injection (100 mg/vial and 500 mg/vial)
Submission Date:	5/30/2017
Submission Type:	Original NDA – 505(b)(2)
Applicant:	Apotex Inc.

Apotex submitted a 505(b)(2) application for *Pemetrexed for Injection (100 mg/vial and 500 mg/vial)* on 5/30/2017. No new clinical pharmacology studies were submitted. The Applicant is relying on FDA's previous findings of safety and effectiveness for the Listed Drug (LD), ALIMTA® (*pemetrexed for injection, 100 mg/vial and 500 mg/vial*) for the clinical pharmacology information needed to support the safety and effectiveness of the proposed pemetrexed product. The proposed product contains the same active ingredient, dosage form, and route of administration as the LD, ALIMTA®; the only difference is the salt form of the active substance. In the proposed Pemetrexed for Injection, a dipotassium salt form of pemetrexed is used instead of the disodium salt used in ALIMTA®. As per 21 CFR 320.22(b)(1), Apotex believes that their product, *Pemetrexed Dipotassium for Injection*, meets the criteria for a waiver of *in vivo* bioavailability and/or bioequivalence studies.

There are no clinical pharmacology issues to be addressed in this NDA for Pemetrexed for Injection and no action is indicated.

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

/s/

SAFAA BURNS
02/23/2018

JEANNE FOURIE ZIRKELBACH
02/23/2018