CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209472Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

Clinical Pharmacology Review Memo

NDA: 209472 (SDN 30)

Submission Date: 8/9/2019

Drug Name: Pemfexy (Pemetrexed Injection)

Dosage Form: 500 mg/20 mL (25 mg/mL)

Applicant: Eagle Pharmaceuticals, Inc. (Eagle)

Submission Type: NDA Amendment – Request for Final Approval

NDA 209472 for Pemfexy (Pemetrexed Injection), *500 mg/20 mL (25 mg/mL)*, was originally submitted on 12/30/2016 (SDN 1) for the treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer and mesothelioma in combination with cisplatin. Pemfexy is a ready-to-dilute liquid intravenous formulation which was developed to eliminate the reconstitution step of the Reference Listed Drug (RLD) ALIMTA. (b) (4) Pemfexy is expected to have the same efficacy and safety profile as for the RLD approved product.

In accordance with the Agency's Tentative Approval Letter dated 10/26/2017, Eagle submitted an amendment request for final approval of their NDA six months prior to the date that this NDA is eligible for final approval. The purpose of this amendment is to provide the legal/regulatory basis for the final approval request, to update the container and carton labeling revised in accordance with the Agency's recommendations dated 12/21/2017 and to update the prescribing information in accordance with the currently approved prescribing information for ALIMTA.

There is no new clinical pharmacology information submitted in this NDA amendment. The updated revised labeling is acceptable from the clinical pharmacology perspective.

Action:
No action is indicated.

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/s/

SAFAA BURNS
10/01/2019 04:35:21 PM

JEANNE FOURIE ZIRKELBACH
10/02/2019 02:39:59 PM

Clinical Pharmacology Review

NDA: 209472 (SDN 1)

Submission Date: 12/30/2016

Drug Name: Pemetrexed Injection

Dosage Form: 25 mg/mL aqueous solution in single-dose vials

Applicant: Eagle Pharmaceuticals, Inc. (Eagle)

Submission Type: Original NDA – 505(b)(2)

Pemetrexed Injection, 25 mg/mL, is a ready-to dilute (RTD) new formulation being submitted in accordance with Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act wherein the pharmacology and safety of this new formulation is based on the established efficacy and safety attributes of the Reference Listed Drug (RLD), ALIMTA (pemetrexed for injection) for Intravenous Use (Eli Lilly's NDA 21462, approval date: 2/4/2004). ALIMTA is being marketed as a sterile single-use vial containing 100 mg or 500 mg of pemetrexed disodium, which upon reconstitution with 0.9% Sodium Chloride Injection contains **25 mg/mL** pemetrexed.

NDA 209472 does **not** contain any clinical or clinical pharmacology studies as the Applicant requests a waiver of the requirement to submit evidence of the *in vivo* bioavailability (BA) or bioequivalence (BE) of *Pemetrexed Injection, 25 mg/mL*, to ALIMTA.

Pemetrexed Injection, 25 mg/mL is intended for the same indications and contains the same active moiety (pemetrexed) as the Reference Listed Drug (RLD) ALIMTA. (b) (4) As both products are aqueous solutions, safety, efficacy and PK profiles are anticipated to be comparable between *Pemetrexed Injection, 25 mg/mL* and ALIMTA.

Action:
No action is indicated.

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/s/

SAFAA BURNS
04/03/2017

JEANNE FOURIE ZIRKELBACH
04/06/2017