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APPLICATION NUMBER:

214408Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY
REVIEW(S)

Clinical Pharmacology Review Memo

NDA: 208419/SDN 1
Submission Date: 1/27/2020
Drug Name: Pemetrexed Injection
Dosage Form: 25 mg/mL (4-mL, 20-mL, 34-mL and 40-mL single-dose vials)
Applicant: Accord Healthcare Inc.
Submission Type: Original 505(b)(2) NDA submission

Pemetrexed Injection is a sterile 25 mg/mL solution of pemetrexed in 4-mL, 20-mL, 34-mL and 40-mL single-dose glass vials for intravenous use. Pemetrexed Injection has the same indications, route of administration and dosing regimens as for the Reference Listed Drug (RLD), ALIMTA (pemetrexed disodium) for injection (500 mg and 100 mg, NDA 21462). The RLD ALIMTA (pemetrexed disodium) requires an initial reconstitution prior to use. ALIMTA has to be first reconstituted with 0.9% sodium chloride injection to get a concentration of 25 mg/mL before further dilution with 0.9% sodium chloride injection (i.e., concentration of 9 mg/mL). Accord's proposed drug product Pemetrexed Injection 25 mg/mL, 4 mL, 20 mL, 34 mL and 40 mL is ready to use (RTU) formulation (to be used after dilution). Pemetrexed Injection is to be administered after dilution with 0.9% sodium chloride injection at concentration of 9 mg/mL in line with RLD. The concentration of drug substance for proposed drug product after dilution will remain same as RLD. The two products are thus considered to be equivalent. Accord requested a waiver of *in-vivo* bioequivalence requirement for Pemetrexed Injection, 25 mg/mL, in accordance with 21CFR.320.22.

There is **no** new clinical pharmacology information submitted in this NDA amendment. Minor changes were made in Section 12.3 (Clinical Pharmacology) of the proposed (b) (4) labeling. All other prescribing information were acceptable from the clinical pharmacology perspective.

Action:

No action is indicated.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SAFAA BURNS
06/11/2020 03:35:43 PM

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06/15/2020 12:04:49 PM