DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 29, 2019

Chih-wei Chen
PharmaCore Biotech Co., Ltd
5F, No. 2 Ln. 31,
Sec 1 Huangdong Rd.,
Tainan Science Park,
Xinshi Dist, Tainai City,
Taiwan 74146

Sent via email to: yukigei@pharmacore-biotech.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to grant permission to submit an ANDA for a generic drug product, Pemetrexed non-lyophilized powder for injection, 100 mg 500 mg, for Intravenous Use, that differs from a reference listed drug (NDA#021462), ALIMTA (Pemetrexed lyophilized powder for injection, 100 mg 500 mg, for Intravenous Use), in its dosage form was received by this office on 05/29/2019.

It was assigned docket number FDA-2019-P-2582. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2019.05.29 13:58:43 -04'00'

Karen P. Malvin
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)