DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 18, 2020

Kenneth E. Surprenant
45 Minges Road West
Battle Creek, MI 49015

Sent via email to: kesbc6@gmail.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA Revise the Drug Label inserts for Fluorouracil and Xeloda (Capecitabine) by:

1) Recommending Pre-Treatment Testing to Identify Patients with Dihydropyrimidine Dehydrogenase (DPD) Deficiency and include the recommendation in the content of the drug labels dealing with:
   a. Patient Counseling
   b. Dosage and Administration
   c. Box Warning.

2) Revising the Patient Counseling Information content to: Shift responsibility for identifying DPD deficiency from the patient to the prescribing physicians who should also discuss with patients the risk associated with DPD deficiency before the start of treatment.

3) Revising the Dosage and Administration content to: Recommend treating physicians pre-screen patients for DPD deficiency and adapt the treatment plan if partial or complete DPD deficiency is identified.

4) Adding a Box Warning that:
   a. Highlights the risk of severe toxicity when treating patients with DPD deficiency, and
   b. Recommends screening for DPD deficiency prior to the start of treatment and prior to resuming treatment after an adverse event that necessitated treatment modification.

Your submission was received by this office on 11/17/2020 and it was assigned docket number FDA-2020-P-2213. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.11.19 11:07:59 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)