March 11, 2022

Karl Schwartz
(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug amend the Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics and require or strongly urge supplementary comparison of Quality of Life-related patient reported outcome (QoL-PROs*) was received and processed under CFR 10.30 by this office on 03/11/2022.

It was assigned docket number FDA-2022-P-0324. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.11 15:30:33 -05'00'

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