FDA U.S. FOOD & DRUG ADMINISTRATION

Karl Schwartz
(b) (6)

September 2, 2022

Re: Docket No. FDA-2022-P-0324

Dear Mr. Schwartz:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 11, 2022. Your petition requests that the Agency amend the 2018 guidance for industry titled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics" to require or strongly urge supplementary comparison of Quality of Life-related patient reported outcomes for certain surrogate endpoints used in randomized controlled cancer clinical trials.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.09.02 09:06:35 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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