



March 15, 2021

Tom Neltner
Environmental Defense Fund
1875 Connecticut Ave. N.W.
Washington, DC 20009

Re: Docket Number FDA-2020-P-2003

Dear Mr. Neltner

This responds to your citizen petition dated September 23, 2020, requesting that the Food and Drug Administration (FDA or we) revise its regulations and associated guidance and forms to ensure that cumulative effect of chemically- or pharmacologically related substances in the diet are taken into account when assessing the safety of a food additive, a food contact substance, a generally recognized as safe substance, or a color additive.

We are advising you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days due to competing priorities. However, be advised that your petition is currently under active evaluation by our staff.

We will contact you when our review is complete, at which time we will inform you of the actions, if any, we decide are appropriate in response to your petition. In the interim, you and other interested parties may continue to submit additional supplemental materials to us for our consideration to the Docket number referenced above.

Sincerely,

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition