



November 15, 2023

Deputy Commissioner Jim Jones  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Request for immediate action on the color additive petition to delist FD&C Red No. 3 for all uses (Docket No. [FDA-2023-N-0437](#))

Dear Deputy Commissioner Jones,

The Center for Science in the Public Interest is writing to urge the US Food and Drug Administration (FDA) to grant our color additive petition (Docket No. [FDA-2023-N-0437](#)) by immediately publishing a notice to delist FD&C Red No. 3 (Red 3) for use in foods, supplements, and ingested drugs. A year has passed since the petition's filing date of November 15, 2022; however, FDA has yet to propose amending regulations to delist Red 3 or substantively respond to our petition.

Per [21 CFR § 71.20](#), FDA has a maximum of 180 days after filing the petition to forward a regulation for publication in the Federal Register or deny the petition. The published regulation "shall list the color additive only for the use or uses...which it may safely be employed." As explained in our petition, there can be no safe use of Red 3 because FDA found that the color additive induces cancer in animals in 1990.<sup>1</sup> Under the Delaney Clause, this finding prohibits the agency from deeming Red 3 as safe for any use, and FDA promised to completely delist the dye more than 30 years ago.<sup>2</sup> Therefore, FDA had 180 days from filing our petition to propose a regulation that lists no safe uses for Red 3 or simply remove the existing regulation.

We request that FDA immediately issue a notice in the Federal Register to delist Red 3 for all remaining uses. Please note that this letter does not provide any substantive information beyond our petition and does not amend the petition. As such, the filing date of November 15, 2022 should remain unchanged.

We thank you for your time and look forward to your quick response.

Sincerely,

Jensen N. Jose, JD  
Regulatory Counsel

Sarah Sorscher, JD, MPH  
Director of Regulatory Affairs

Thomas M. Galligan, PhD  
Principal Scientist for Food Additives & Supplements

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<sup>1</sup> Center for Science in the Public Interest. Red 3 Petition. P. 9. October 24, 2022. <https://www.cspinet.org/resource/red-3-petition>. Accessed November 9, 2023.

<sup>2</sup> *Id.*