CENTER FOR Science IN THE Public Interest
The nonprofit publisher of Nutrition Action

November 15, 2024

James Jones
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration
Jim.Jones@fda.hhs.gov

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,

As two years have passed since we filed our petition on FD&C Red No. 3 (Red 3) on November 15, 2022, the Center for Science in the Public Interest (CSPI) urges the U.S. Food and Drug Administration (FDA) to grant our color additive petition (Docket No. FDA-2023-N-0437) by immediately publishing a notice to delist the dye for use in foods, supplements, and ingested drugs. While the FDA confirmed receipt and posted our petition for public comment, the agency has yet to rule on our petition.

By now, the FDA should have proposed and issued a final rule on Red 3 as our petition is not legally or scientifically complex. The scientific basis for our petition is simple: the FDA concluded that Red 3 causes cancer in animals, and no studies since 1990 call that prevailing conclusion into question.[1] Legally, the Delaney Clause clearly prohibits the FDA from deeming Red 3 as safe after the agency itself deemed it a carcinogen.[2]

Further, the FDA's deadline to ban Red 3 was May 14, 2023, as the agency only has 180 days after filing a color additive petition to forward a regulation for publication in the Federal Register or deny the petition. Per 21 CFR § 71.20(a)(2), the published regulation "shall list the color additive only for the use or uses…for which it may safely be employed."[3] It has been two years since our petition was filed, and the FDA has yet to rule on our petition, much less propose a rule banning the color additive, the initial step towards issuing a final regulation.

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[1] Center for Science in the Public Interest, et al. *Color Additive Petition pursuant to 21 U.S.C. §§ 379e, 721(B)(1) to Remove FD&c Red No. 3 from the Permanent List of Color Additives Approved for Use in Food and Dietary Supplements, 21 C.F.R. § 74.303, and for Use in Ingested Drugs, 21 C.F.R. § 74.1303, Because the FDA Has Found That the Additive Induces Cancer and Is Unsafe.* 24 Oct. 2022, www.cspinet.org/sites/default/files/2022-10/Red%203%20petition_24%20Oct%202022_FINAL%20%281%29.pdf. Accessed 14 Nov. 2024.

[2] *Id.*

[3] 21 CFR § 71.20(a)(2). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-71/subpart-B/section-71.20.

We request that the 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. Please direct correspondence to Jensen Jose, jjose@cspinet.org, 202-777-8367.

Sincerely,

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