WORLD TRADE ORGANIZATION

G/SPS/N/USA/3368

24 February 2023

(23-1328)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	**Notifying Member:** UNITED STATES OF AMERICA **If applicable, name of local government involved:**
2.	**Agency responsible:** Food and Drug Administration (FDA)
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Inorganic or mineral colouring matter, n.e.s.; preparations based on inorganic or mineral colouring matter of a kind used for colouring any material or produce colorant preparations (excl. preparations of heading 3207, 3208, 3209, 3210, 3213 and 3215); inorganic products of a kind used as luminophores, whether or not chemically defined (HS code(s): 3206); Food technology (ICS code(s): 67)
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** **[X] All trading partners** **[ ] Specific regions or countries:**
5.	**Title of the notified document:** Filing of Color Additive Petition From Center for Science in the Public Interest, et al.; Request To Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs; Petition for Rulemaking. **Language(s):** English. **Number of pages:** 2 https://www.govinfo.gov/content/pkg/FR-2023-02-17/pdf/2023-03391.pdf
6.	**Description of content:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Center for Science in the Public Interest, et al., proposing that FDA repeal the color additive regulations providing for the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs.
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests.**
8.	**Is there a relevant international standard? If so, identify the standard:** **[ ] Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:** **[ ] World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:** **[ ] International Plant Protection Convention *(e.g. ISPM number)*:** **[X] None** **Does this proposed regulation conform to the relevant international standard?** **[ ] Yes [ ] No** **If no, describe, whenever possible, how and why it deviates from the international standard:**

9. **Other relevant documents and language(s) in which these are available:**

10. **Proposed date of adoption *(dd/mm/yy)*:** Not applicable

Proposed date of publication *(dd/mm/yy)*: Not applicable

11. **Proposed date of entry into force: [ ] Six months from date of publication, and/or *(dd/mm/yy)*:** Not applicable

[ ] Trade facilitating measure

12. **Final date for comments: [ ] Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 18 April 2023. The color additive petition was filed on 15 November 2022. Either electronic or written comments must be submitted by 18 April 2023.

Agency or authority designated to handle comments: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Electronic Submissions
Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comment, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions
Submit written/paper instructions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include the Docket No. FDA– 2023–N–0437 for "Filing of Color Additive Petition from Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs". Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as "Confidential Submissions", publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, +(240) 402 7500.

13. **Text(s) available from: [ ] National Notification Authority, [ ] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

Text can be found in the Federal Register, Vol. 88, No. 33, Page 10245 or on the internet at: https://www.govinfo.gov/content/pkg/FR-2023-02-17/pdf/2023-03391.pdf.