



17 January 2025

(25-0459)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

Addendum

The following communication, received on 17 January 2025, is being circulated at the request of the Delegation of the United States of America.

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; Final Amendment; Order

The Food and Drug Administration (FDA or we) is granting a color additive petition submitted by Center for Science in the Public Interest, et al., by repealing the color additive regulations that permit the use of FD&C Red No. 3 in foods (including dietary supplements) and in ingested drugs. The petitioners provided data demonstrating that this additive induces cancer in male rats. Therefore, FDA is revoking the authorized uses in food and ingested drugs of FD&C Red No. 3 in the color additive regulations.

DATES: This order is effective 15 January 2027, except for amendatory instruction 4, which is effective 18 January 2028. If any provisions are delayed or stayed by the filing of proper objections, FDA will publish such notification in the Federal Register. Submit either electronic or written objections and requests for a hearing on the order by 18 February 2025.

<https://www.govinfo.gov/content/pkg/FR-2025-01-16/pdf/2025-00830.pdf>
https://members.wto.org/crnattachments/2025/SPS/USA/25_00738_00_e.pdf

This addendum concerns a:

- Modification of final date for comments
- Notification of adoption, publication or entry into force of regulation
- Modification of content and/or scope of previously notified draft regulation
- Withdrawal of proposed regulation
- Change in proposed date of adoption, publication or date of entry into force
- Other:

Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)

- Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Not applicable

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:

You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of 18 February 2025. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on <https://www.regulations.gov>.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions 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 objections 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 "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 objections, those filed in a timely manner (see ADDRESSES), 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.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, +(240) 402 7500.

For further information contact: Shayla West-Barnette, Office of Pre- market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 1262; or Alexandra Beliveau, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 2378.

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. 90, No. 10, Page 4628 or on the Internet at: <https://www.govinfo.gov/content/pkg/FR-2025-01-16/pdf/2025-00830.pdf>
