4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2026-N-6304]

Proposal to Revoke the Color Additive Listing for Use of Citrus Red No. 2 on the Skins of Mature Oranges

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to issue an order that would repeal the color additive regulation that allows for the use of Citrus Red No. 2 for coloring the skins of mature oranges. Based on certification data, it appears that Citrus Red No. 2 is no longer used for coloring the skins of oranges and has not been certified for use as a color additive in food marketed in the United States since 2020. Because the authorized use of Citrus Red No. 2 appears to have been abandoned, we have tentatively concluded that this color additive regulation is outdated and unnecessary.

DATES: Submit electronic or written comments on the proposed order by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments 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 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 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 comments submitted to the Dockets Management Staff, FDA will post your comment, 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-2026-N-6304 for "Proposal to Revoke the Color Additive Listing for Use of Citrus Red No. 2 on the Skins of Mature Oranges." Received comments, 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.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

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 Meridith L. Kelsch, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

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I. Background

President Trump has directed the heads of executive departments and agencies to eliminate unnecessary and burdensome regulations (Executive Order 14192, "Unleashing Prosperity Through Deregulation" (90 FR 9065, Feb. 6, 2025)). Independently, Secretary Kennedy has expressed support for deregulatory initiatives across all HHS components to focus on the core mission to Make America Healthy Again (see "Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again" (90 FR 20478, May 14, 2025)). Removing the color additive regulation for Citrus Red No. 2, which we tentatively conclude is no longer used for its authorized use in food in the United States, is consistent with these directives. It is also consistent with Executive Order 13563, "Improving Regulation and Regulatory Review" (76 FR 3821, Jan. 21, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those "that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them," accordingly.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate "color additives" (see section 721(b) of the FD&C Act (21 U.S.C. 379e(b))). The FD&C Act defines "color additive," in relevant part, as a material which is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and that when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting color (see section 201(t) of the FD&C Act (21 U.S.C. 321(t))). Color additives used in or on a food, drug, cosmetic, or certain medical devices are deemed unsafe and prohibited except to the extent that we approve their use through issuance of a regulation and, when subject to certification, are batch certified, unless an exemption applies (see section 721(a) and (c) of the FD&C Act).

Sections 701(e), (f), and (g) of the FD&C Act (21 U.S.C. 371(e), (f), and (g)) apply to the issuance, amendment, or repeal of color additive regulations (see section 721(d) of the FD&C Act). Section 701(e) of the FD&C Act provides that any action for the issuance, amendment, or repeal of a color additive regulation may be initiated by a proposal made by the Secretary or by a petition of any interested persons. It further requires that FDA publish such a proposal, provide an opportunity for interested parties to present their views, and then by order act upon such proposal.

FDA may issue a regulation listing a color additive for use in or on food, drugs, devices, or cosmetics only if it determines that the additive is suitable and safe for such use (see section 721(b)(2)(A) of the FD&C Act). The regulation that permits the use of a color additive includes appropriate limitations and requirements for its safe use and specifies whether certification is required (see section 721(a)(1), (c) of the FD&C Act; 21 CFR 71.20). (For additional information on certification of color additives, see Color Certification FAQs, available at: https://www.fda.gov/industry/color-certification/color-certification-faqs.)

FDA determines the need for batch certification based on whether the color additive composition needs to be controlled to protect the public health (see 21 CFR 71.20(b)). Some color additives, in their uncertified forms, might contain impurities at levels that pose a health concern. When batch certification is required for a color additive, the color additive must be batch certified by FDA. If it is not batch certified, it is deemed unsafe under the relevant adulteration provision, for example, under section 402(c) of the FD&C Act (21 U.S.C. 342(c)) for food (see section 721(a)(1) of the FD&C Act). To receive certification for a color additive, a request must be filed with FDA, along with a batch sample. FDA assesses the information in the

request and analyzes whether the batch sample conforms to the applicable identity and specifications stated in the listing regulation for the color additive. If FDA finds that the batch sample meets the applicable requirements for composition and purity stated in the listing regulation, FDA will issue a certificate indicating the lot number for the batch and stating that the batch is certified (see 21 CFR 80.21, 80.31).

II. Description of the Proposed Order

On May 22, 1963 (28 FR 5082),[1] we issued a regulation allowing for the use of Citrus Red No. 2 as a color additive on the skins of oranges that are not intended or used for processing (or, if so used, are designated in the trade as "packing-house elimination"), and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown (*i.e.*, mature oranges), subject to certain specifications, restrictions, labeling requirements, and certification. Under 21 CFR 74.302, Citrus Red No. 2, oranges colored with Citrus Red No. 2 must bear not more than 2.0 parts per million of the color additive, calculated on the basis of the weight of the whole fruit. Citrus Red No. 2 is not authorized for other uses as a color additive. The regulation also specifies that all batches of Citrus Red No. 2 must be certified in accordance with our regulations under 21 CFR part 80.

Our records indicate that Citrus Red No. 2 was last batch certified in 2020 and that FDA has not received any requests to batch certify Citrus Red No. 2 since that time (Ref. 1). We tentatively conclude that the absence of requests to certify a batch of Citrus Red No. 2 since 2020 indicates that the color additive is no longer manufactured for uses established in § 74.302. Without a certification, Citrus Red No. 2 may not be used as a color additive in food in the United States. Considering this information, we tentatively conclude that the authorized use of Citrus Red No. 2 has been abandoned. Therefore, we tentatively conclude that the color additive listing for Citrus Red No. 2 at § 74.302 is outdated and unnecessary and we propose to repeal this color additive regulation. To facilitate the phase-out of any remaining batch certified Citrus Red No. 2 supply that may be in use, we propose to provide an extended effective date and a compliance date to allow for its depletion.

If this proposed order is finalized, in accordance with 21 CFR 80.32(h), all certificates for any existing batches and portions of batches of Citrus Red No. 2 would cease to be effective for use in food on the effective date for the removal of § 74.302, and any lots of Citrus Red No. 2 would be regarded as uncertified after that date. The use of Citrus Red No. 2 in any food after its certificate ceases to be effective would result in such food being adulterated. However, as

[1] On April 17, 1959 (24 FR 2945), we published a temporary listing for the use of Citrus Red No. 2.

indicated below, we propose to provide a compliance date to allow for depletion of any remaining certified batches of Citrus Red No. 2, after the effective date.

III. Proposed Effective Date and Compliance Date of a Final Order

We propose that any final order based on this proposed order be effective 90 days following its publication in the *Federal Register*. In the event that the food industry needs time to use up existing reserves of certified batches of Citrus Red No. 2, FDA proposes to not enforce applicable requirements of a final order with regard to food products manufactured (domestically and internationally) until one year after the effective date of that final order. We request comments on whether to provide such a compliance period and the appropriate duration.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 2). Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) is not required.

VI. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Memorandum from S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, Human Foods Program, FDA, to M. Honigfort, Division of Food Ingredients, Regulatory Management Branch, Human Foods Program, FDA, June 26, 2026.

2. Memorandum from M. Pfeil, Environmental Review Team, Office of Pre-Market Additive Safety, Human Foods Program, FDA, to S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, Human Foods Program, FDA, June 26, 2026.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose to amend 21 CFR part 74 as follows:

PART 74 – LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.302 [Removed]

2. Remove § 74.302.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-14909 Filed: 7/22/2026 8:45 am; Publication Date: 7/23/2026]