Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2025–C–3543]

Proposal To Remove the Color Additive Listing for Use of Orange B on Casings or Surfaces of Frankfurters and Sausages

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 remove the color additive regulation that allows for the use of Orange B for coloring the casings or surfaces of frankfurters and sausages. Based on certification data, it appears that Orange B is no longer used for coloring the casings or surfaces of frankfurters and sausages and has not been certified for use as a color additive in food marketed in the United States since 1978. Because the authorized use of Orange B appears to have been abandoned, we have tentatively concluded that this color additive regulation is outdated and unnecessary.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 October 17, 2025.

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 October 17, 2025. 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–2025–C–3543 for ''Proposal to Remove the Color Additive Listing for Use of Orange B on Casings or Surfaces of Frankfurters and Sausages.'' 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 Premarket 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, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

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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 Orange B, 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 us 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 (see section 721(a) 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 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 January 4, 1966 (31 FR 8), we issued a regulation allowing for the use of Orange B as a color additive in casings for frankfurters and sausages, subject to certain specifications, restrictions, labeling requirements, and certification. Under § 74.250 (21 CFR 74.250), Orange B is authorized for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food. It is not authorized for other uses as a color additive. The regulation also specifies that all batches of Orange B must be certified in accordance with our regulations under 21 CFR part 80.

Our records indicate that Orange B was last batch certified in 1978 and that FDA has not received any requests to batch certify Orange B since that time (Ref. 1). We tentatively conclude that the absence of requests to certify a batch of Orange B since 1978 indicates that the color additive is no longer manufactured for uses established in § 74.250. Without a certification, Orange B 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 Orange B has been abandoned. Therefore, we tentatively conclude that the color additive listing for Orange B at § 74.250 is outdated and unnecessary and we propose to repeal this color additive regulation. We would consider this action to also partially respond to the Center for Science in the Public Interest's (CSPI) 2008 citizen petition (Docket No. FDA–2008–P–0349), which requests, in part, that FDA revoke the color additive approval of Orange B.

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 Orange B would cease to be effective for use in food on the effective date for the removal of § 74.250, and any lots of Orange B would be regarded as uncertified after that date. The use of Orange B in any food after its certificate ceases to be effective would result in such food being adulterated.

III. Proposed Effective Date of a Final Order

We propose that any final order based on this proposed order be effective 45 days following its publication in the **Federal Register**.

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. 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 reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it also is 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 Review Branch, Human Foods Program, FDA, August 19, 2025.

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.

§ 74.250 [Removed]

■ 2. Remove § 74.250.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18023 Filed 9–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF EDUCATION

34 CFR Part 75

[Docket ID ED–2025–OS–0745]

Proposed Priority and Definitions—Secretary's Supplemental Priority and Definitions on Promoting Patriotic Education

AGENCY: U.S. Department of Education.

ACTION: Proposed priority and definitions.

SUMMARY: The Secretary proposes one additional priority and related definitions for use in currently authorized discretionary grant programs or programs that may be authorized in the future. The Secretary may choose to use the entire priority for a grant program or a particular competition or use one or more of the priority's component parts. This priority and definitions augment other Secretary's Supplemental Priorities, such as the initial set of three Secretary's Supplemental Priorities on Evidence-Based Literacy, Educational Choice, and Returning Education to the States published as final priorities on September 9, 2025, (90 FR 43514) and the additional Secretary's Supplemental Priority on Artificial Intelligence published as a proposed priority on July 21, 2025 (90 FR 34203).

DATES: We must receive your comments on or before October 17, 2025.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *Regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for more details.

FOR FURTHER INFORMATION CONTACT: Zachary Rogers, U.S. Department of Education, 400 Maryland Avenue SW, Room 7W213, Washington, DC 20202–6450. Telephone: (202) 260–1144. Email: *SSP@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed priority and definitions. Comments must be submitted via the Federal eRulemaking Portal at *Regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *Regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments by fax or by email, or comments submitted after the comment period closes. To ensure that the Department does not receive duplicate copies, please submit your comments only once. Additionally, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.Regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.'' Also included on *Regulations.gov* is a commenter checklist that addresses how to submit effective comments.

In instances where individual submissions appear to be duplicates or near duplicates of comments prepared as part of a writing campaign, the Department may choose to post to *Regulations.gov* one representative sample comment along with the total comment count for that campaign. The Department will consider these comments along with all other comments received. In instances where individual submissions are bundled together (submitted as a single document or packaged together), the Department will post all of the substantive comments included in the submissions along with the total comment count for that document or package to *Regulations.gov.* Comments containing personal threats will not be posted to *Regulations.gov* and may be referred to the appropriate authorities.

During and after the comment period, you may inspect public comments about the proposed priority and definitions by accessing *Regulations.gov.* To inspect comments in person, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Privacy Note: The Department's policy is to generally make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *Regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this document. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Program Authority: 20 U.S.C. 1221e–3, 3474.

Proposed Priority: This document contains one proposed priority.

Proposed Priority: Promoting Patriotic Education.

Background: The success of the American experiment in self-government requires the cultivation of both citizenship competency and informed patriotism among the American People. Citizens must understand why our free-market economy is a highly evolved system of cooperation fostered by our constitutional republic, and how it functions to secure the blessings of liberty for all Americans. This understanding can only be acquired and prove to be lasting when rooted in a