



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2025-C-3543]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing an order to repeal the color additive regulation that allows for the use of Orange B for coloring the casings or surfaces of frankfurters and sausages. We have determined that the authorized use of Orange B has been abandoned, and we have concluded that this color additive regulation is outdated and unnecessary. Therefore, FDA is revoking the authorized use in food of Orange B in the color additive regulations.

DATES: This order is effective [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section VII for further information on the filing of objections.

ADDRESSES: 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. 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-2025-C-3543 for “Revocation of the Color Additive Listing for Use of Orange B on Casings or Surfaces of Frankfurters and Sausages.” 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.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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 objections. 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 objections 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. Introduction

In the *Federal Register* of September 17, 2025 (90 FR 44786), we issued a proposal to repeal the color additive regulation that allows for the use of Orange B for coloring the casings or surfaces of frankfurters and sausages. We stated that 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. We tentatively concluded that this color additive regulation is outdated and unnecessary because the authorized use of Orange B appears to have been abandoned.

The proposal gave interested parties until October 17, 2025, to submit comments on the proposed order. This order finalizes the action described in the proposed order.

II. 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 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, 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 persons 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).

Under § 74.250 (21 CFR 74.250), Orange B is authorized for coloring the casings or surfaces of frankfurters and sausages, subject to certain specifications, restrictions, labeling requirements, and certification. 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 in 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. 1¹). Because Orange B may not be used as a color additive in food in the United States without a certification, we conclude that the authorized use of Orange B has been abandoned and that the color additive listing for Orange B in § 74.250 is outdated and unnecessary.

III. Comments on Proposed Order and FDA Responses

FDA received 16 comments in response to the proposed order. All but one of the comments supported revoking the color additive listing for Orange B in § 74.250. None of the comments claimed or provided evidence that Orange B is still in use as a color additive for coloring the casings or surfaces of frankfurters and sausages or that there are any remaining certified batches.

In this section, we summarize and respond to relevant portions of the comments. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment is for

¹ We note that this referenced memorandum (Ref. 1) is the same as the referenced memorandum provided in the proposed order, however, the References section of the proposed order incorrectly listed the date of the referenced memorandum as August 19, 2025. The correct date of September 12, 2025, is reflected in the referenced material provided in the docket.

organizational purposes only and does not signify the comment's value, importance, or the order in which it was submitted.

(Comment 1) Several comments supported the proposed action to repeal the color additive regulation that allows for the use of Orange B because the regulation is outdated or unnecessary.

(Response 1) We agree that the color additive listing for Orange B in § 74.250 is outdated and unnecessary. 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). Because Orange B may not be used as a color additive in food in the United States without a certification, we conclude that the authorized use of Orange B has been abandoned and that the color additive listing for Orange B in § 74.250 is outdated and unnecessary.

(Comment 2) A few comments thought that Orange B and color additives are considered generally recognized as safe (GRAS) and indicated that FDA should remove Orange B from being considered GRAS and similarly reevaluate other color additives that are considered GRAS.

(Response 2) These comments incorrectly assert that Orange B and color additives are considered GRAS. We clarify that color additives, including Orange B, cannot be GRAS because there is no GRAS provision for color additives. See sections 201(s) and 409 of the FD&C Act (21 U.S.C. 321(s) and 348); see also 21 CFR 170.3 and 170.30 (explaining eligibility for classification as GRAS). Therefore, the color additive Orange B is not considered GRAS.

(Comment 3) Several comments expressed concerns that synthetic color additives used in foods such as Orange B, could be associated with health risks, and one comment questioned whether Orange B had fallen out of use as a result of health implications.

(Response 3) The proposed order provided information about the history of § 74.250 (Ref. 1). As that information indicated, by the late 1970s, there were some evaluations by the one manufacturer of Orange B, as well as others, of potential health implications associated with

Orange B, which led to discontinuation of its production. Consistent with that, as explained in the proposed order, 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. The safety of synthetic color additives used in foods, generally, is beyond the scope of this action.

IV. Conclusion

Based on our review of the batch certification data for Orange B, comments, and other relevant information, we have determined that the authorized use of Orange B has been abandoned, and we conclude that this color additive regulation is outdated and unnecessary. FDA is revoking the authorization for this substance as a color additive to no longer provide for the use of Orange B for coloring the casings or surfaces of frankfurters and sausages. Therefore, we are amending 21 CFR part 74 as set forth in this document. We consider this action also to be partially responsive to the Center for Science in the Public Interest's 2008 citizen petition (Docket No. FDA-2008-P-0349), which requested, in part, that FDA revoke the color additive approval of Orange B.

In accordance with 21 CFR 80.32(h), all certificates for existing batches and portions of batches of Orange B will cease to be effective for use in food on the effective date for the removal of § 74.250, and any lots of Orange B will be regarded as uncertified after that date. The use of Orange B in any food after its certificate ceases to be effective will result in such food being adulterated.

V. Analysis of Environmental Impacts

We previously considered the environmental effects of this order, as stated in the proposed order (90 FR 44786, September 17, 2025). We stated that we had 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 such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VI. Paperwork Reduction Act of 1995

This order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

This order is effective as shown in the DATES section, except as to any provisions that may be stayed by the filing of proper objections under sections 701(e)(2) and 721(d) of the FD&C Act (21 U.S.C. 371(e)(2) and 379e(d)). If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>. We will publish notice of the objections that we have received or lack thereof in the *Federal Register*.

VIII. 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 are also 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, September 12, 2025.

2. Memorandum from M. Pfeil, 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 24, 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, 21 CFR part 74 is amended 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.