4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2024-C-1085]

Listing of Color Additive Exempt From Certification; Beetroot Red; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a delay of the effective date of our February 6, 2026, final order to amend the color additive regulations to provide for the safe use of beetroot red for the coloring of human foods generally, at levels consistent with current good manufacturing practice, except in products under the jurisdiction of the United States Department of Agriculture (USDA), infant formula, or foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the use of the added color is authorized by such standards. The delay of the effective date is required by law following the filing of timely objections on the final order. This announcement does not reflect a change in our determination that there is a reasonable certainty of no harm from the use of this color additive under the conditions of its intended use. In addition, this announcement does not constitute a determination that all of the issues raised in the relevant submission constitute objections or that a hearing is justified on any objections that have been filed.

DATES: As of March 20, 2026, the effective date of the final order published February 6, 2026 (91 FR 5295) is delayed indefinitely. The Food and Drug Administration will publish a document in the Federal Register announcing a new effective date or other administrative action on the order.

FOR FURTHER INFORMATION CONTACT: Christopher Kampmeyer, Office of Pre-Market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1255; or Meadow Platt, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 6, 2026 (91 FR 5295), FDA issued a final order, *Listing of Color Additives Exempt from Certification; Beetroot Red*, to provide for the safe use of beetroot red for the coloring of human foods generally, at levels consistent with current good manufacturing practice, except in products under the jurisdiction of USDA, infant formula, or foods for which standards of identity have been issued under section 401 of the FD&C Act, unless the use of the added color is authorized by such standards. Specifically, the final order added a new § 73.39, titled "Beetroot red," (21 CFR 73.39). We issued the final order in response to a color additive petition submitted by Phytolon, Ltd. We gave interested persons until March 9, 2026, to file objections and requests for a hearing on the final order.

We received a submission from GMO/Toxin Free USA containing objections that meet the conditions set forth in 21 CFR 12.22 to initiate a stay of the effective date of the final order. See Submission from GMO/Toxin Free USA, to the Dockets Management Staff, Food and Drug Administration, dated March 5, 2026, at pages 1-6. In addition to the objections submitted by GMO/Toxin Free USA, we received other comments that opposed the final order, but none of them appear to be an objection under 21 CFR 12.22 nor do any of them request a hearing. We plan to address the objections in a future document.

Under sections 701(e)(2) and 721(d) of the FD&C Act (21 U.S.C. 371(e)(2) and 379e(d)), within 30 days after publication of an order relating to a color additive regulation, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a

public hearing upon such objections. The filing of the objections operates to delay the effective date of the final order until we take final action on the objections.[1] Our announcement of the delay of the effective date of the final order does not reflect a change in our determination that there is a reasonable certainty of no harm from the use of this color additive under the proposed conditions of its intended use. In addition, this notification does not constitute a determination that all of the issues raised in the submission constitute objections or that a hearing is justified on any submissions that have been filed.

For access to the docket to read the objections received, go to https://www.regulations.gov and insert the docket number FDA-2024-C-1085 into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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[1] Although the statute uses the word "stay," this delay effectuates the same result.