



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2024-C-3384]

Listing of Color Additive Exempt From Certification; Spirulina Extract; 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 expanded safe use of spirulina (*Arthrospira platensis*) extract as a color additive in human foods generally (except for infant formula, certain foods subject to regulation by the U.S. Department of Agriculture (USDA), and 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) at levels consistent with good manufacturing practice (GMP); to lower the heavy metal specifications for lead, arsenic, and mercury; and to add a specification for cadmium. The delay of the effective date is required by law following the filing of timely objections and a request for a hearing 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 submission constitute objections or that a hearing is justified on any objections or requests for a hearing that have been filed.

DATES: As of March 20, 2026, the effective date of the final order published February 6, 2026 (91 FR 5291) 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: Marissa Santos, Office of Pre-Market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-8160; 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.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 6, 2026 (91 FR 5291), FDA issued a final order, *Listing of Color Additives Exempt from Certification; Spirulina Extract*, to provide for the expanded safe use of spirulina (*Arthrospira platensis*) extract as a color additive in human foods generally (except for infant formula, certain foods subject to regulation by the USDA, and 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) at levels consistent with good manufacturing practice (GMP); to lower the heavy metal specifications for lead, arsenic, and mercury; and to add a specification for cadmium. Specifically, the final order amended § 73.530, titled “Spirulina extract,” (21 CFR 73.530). We issued the final order in response to a color additive petition submitted by GNT USA, LLC. We gave interested persons until March 9, 2026, to file objections and requests for a hearing on the final order.

Obelisk Tech Systems Inc. submitted objections and a request for a hearing. See Submission from Obelisk Tech Systems Inc., to the Dockets Management Staff, Food and Drug Administration, submitted March 7, 2026. In addition to the objections and request for a hearing submitted by Obelisk Tech Systems Inc, we received another comment that opposed the final order, but does not appear to be an objection under 21 CFR 12.22 nor does it request a hearing. We plan to address the objections and request for a hearing 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 objections or requests for hearing 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-3384 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.