

# Food Color Additive Update: FDA Places Beetroot Red Approval and Expanded Spirulina Extract Approval on Hold

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**PRACTICES** FDA Regulatory and Compliance, Food, Beverage and Restaurant

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After receiving objections from stakeholders, the U.S. Food and Drug Administration (FDA) has indefinitely delayed its approval of the use of beetroot red and expanded approved use of spirulina extract as color additives in human foods.<sup>1</sup>

## Approval of Beetroot Red

The FDA's February 6, 2026 final order amended color additive regulations to provide for the safe use of beetroot red at levels consistent with current good manufacturing practice, except in products under USDA jurisdiction, in infant formula, and in foods with standards of identity under Section 401 of the federal Food, Drug and Cosmetic Act (the "FD&C Act").

The FD&C Act allows "any person adversely affected" to object to such an order within 30 days and to request a hearing to delay the effective date until the FDA reviews the objections.<sup>2</sup>

GMO/Toxin Free USA (TFUSA) filed a timely objection to delay the approval of beetroot red as a color additive.<sup>3</sup> TFUSA alleged that the beetroot red dye being evaluated is produced using genetic engineering and that it is not natural, but it is in fact synthetic.<sup>4</sup> The FDA's final order reveals that the first step in manufacturing beetroot red is "construction of the *S. cerevisiae* production strain that is genetically engineered to express the genes involved in the biosynthesis of betanin."<sup>5</sup> TFUSA alleges that the FDA did not sufficiently evaluate this fermented and genetically engineered form of beetroot red but instead relied on data from studies on natural beetroot juice or natural betalains in its determination.<sup>6</sup> TFUSA argues that not only is the safety assessment inadequate, but that the approval of this synthetic form of beetroot red is also in contrast to the agency's recently announced initiative to phase out certain synthetic dyes in favor of naturally derived ones.<sup>7</sup>

The current definition of "artificial color" applies to all color additives, whether derived from natural or synthetic sources.<sup>8</sup> Earlier this year, to help ease food manufacturers' transition from synthetic to natural food dyes, the FDA announced that it would not take enforcement action against firms making certain voluntary labeling claims on foods intended for human consumption that do not contain FD&C Act certified colors.<sup>9</sup> The FDA stated that it will use enforcement discretion on voluntary label claims like "made without artificial food colors/colorings," "no artificial color/colors/coloring" and "no added artificial color/colors/coloring" as long as the food contains none of the colors listed in 21 CFR part 74.<sup>10</sup>

## Expanded Approval of Spirulina Extract

Obelisk Tech Systems, Inc. objected to the FDA’s expanded approval of spirulina extract as a color additive because it alleges that several vital safety assessments were not performed, such as dietary exposure, cadmium carcinogenicity status, and microcystin toxin analysis.<sup>11</sup>

## What’s Next?

The FDA has not yet published hearing dates related to the objections.<sup>12</sup> The FDA has clarified that its announcement to delay the effective date of the final orders does not reflect a change in its determination that “there is a reasonable certainty of no harm” from the use of beetroot red and spirulina extract as color additives under the proposed conditions of intended use, and that the FDA will evaluate the objections before moving forward with the final orders.<sup>13</sup> Pending review, the FDA will address the objections at a later date.<sup>14</sup>

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<sup>1</sup> U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Beetroot Red; Delay of Effective Date](#), 91 Fed. Reg. 13965 (Mar. 24, 2026); U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Spirulina Extract; Delay of Effective Date](#), 91 Fed. Reg. 13966 (Mar. 24, 2026) (citing U.S. Food and Drug Admin., [Listing of Color Additives Exempt From Certification; Beetroot Red](#), 91 Fed. Reg. 5295 (Feb. 6, 2026); U.S. Food and Drug Admin., [Listing of Color Additives Exempt From Certification; Spirulina Extract](#), 91 Fed. Reg. 5291 (Feb. 6, 2026)).

<sup>2</sup> 21 USC 371(e)(2), 379e(d).

<sup>3</sup> U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Beetroot Red; Delay of Effective Date](#), 91 Fed. Reg. 13965 (Mar. 24, 2026); U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Spirulina Extract; Delay of Effective Date](#), 91 Fed. Reg. 13966 (Mar. 24, 2026).

<sup>4</sup> [Toxin Free USA Campaigns To Prevent Products of Genetic Engineering From Being Labeled “Natural”](#), ToxinFreeUSA.org (Apr. 3, 2026) (citing U.S. Food and Drug Admin., [Comment from GMO/Toxin Free USA](#), No. FDA-2024-C-1085-0003 (Mar. 20, 2026)).

<sup>5</sup> U.S. Food and Drug Admin., [Listing of Color Additives Exempt From Certification; Beetroot Red](#), 91 Fed. Reg. 5295, 5296 (Feb. 6, 2026).

<sup>6</sup> [Comment from GMO/Toxin Free USA](#), No. FDA-2024-C-1085-0003 (Mar. 20, 2026).

<sup>7</sup> *Id.* (citing U.S. Food and Drug Admin., *HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation’s Food Supply* (Apr. 22, 2025)).

<sup>8</sup> 21 CFR 101.22(a)(4) (citing 21 CFR 70.3(f)).

<sup>9</sup> U.S. Food and Drug Admin., [Letter to the Food Industry on “No Artificial Colors” Labeling Claims](#) (Feb. 5, 2026).

<sup>10</sup> *Id.* (citing 21 CFR part 74).

<sup>11</sup> U.S. Food and Drug Admin., [Comment from Obelisk Tech Systems Inc. CEO James H. Poole](#), No. FDA-2024-C-3384-0003 (Mar. 7, 2026).

<sup>12</sup> U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Beetroot Red; Delay of Effective Date](#), 91 Fed. Reg. 13965 (Mar. 24, 2026); U.S. Food and Drug Admin., [Listing of Color Additive Exempt From Certification; Spirulina Extract; Delay of Effective Date](#), 91 Fed. Reg. 13966 (Mar. 24, 2026).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*