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Client Alert Commentary

Latham & Watkins FDA Regulatory Practice

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HHS, FDA Announce Plans to Remove Certain Color Additives From Food

Food product manufacturers should prepare for FDA to pursue statutory and regulatory changes to phase out the use of certified color additives in food.

Key Points:

- None of the announced measures includes a ban on the use of the most widely used color additives in food — and drugs — but statements from Health and Human Services Secretary Robert F. Kennedy, Jr. and FDA Commissioner Martin Makary suggest FDA will pursue legal options to implement this change if industry does not voluntarily comply.
- Secretary Kennedy's comments signaled that FDA will take similar measures to prohibit the use of other widely used food substances, but he acknowledged legal limitations on this plan.
- FDA intends to authorize the use of four new "natural color additives," which would allow industry to use these substances as color additives in their products, but whether batches of these additives would require FDA certification remains unclear.
- Commissioner Makary also noted that FDA is taking action to remove these dyes "from medications." FDA did not disclose any plans to revoke or modify its regulations authorizing the use of these color additives in drugs, but drug product manufacturers should be prepared for this possibility.

On April 22, 2025, HHS and FDA announced a series of highly anticipated measures aimed at removing from the nation's food supply all "petroleum-based synthetic dyes" — i.e., color additives that require batch certification under Subpart A of 21 C.F.R. Part 74 in order to be authorized for use in a food product.[1]

The measures stop short of immediately banning the six most commonly used color additives in food, which include FD&C Red No. 40 and FD&C Yellow No. 6. Instead, they describe a longer-term process that appears to contemplate an appeal for voluntary industry action to stop using the six most commonly used color additives, in conjunction with a legal proceeding to revoke or modify the rulemakings that authorize the current use of Orange B and Citrus Red No. 2, two less commonly used additives.

The announcement represents a significant step forward in the Trump administration's broader initiative to enhance FDA's regulatory oversight over the nation's food supply. Underscoring this commitment, Secretary Kennedy pledged in the Live Announcement that "[o]ne by one we're going to get rid of every

ingredient and additive in . . . food that we can legally address," and that "[e]very synthetic chemical that doesn't belong in a school lunch is on notice."[2]

Overview of New Measures

The announcements this week outline that, as part of the administration's broader Make America Healthy Again initiative, FDA will take the following actions to phase out all "petroleum-based synthetic dyes" from the nation's food supply:

- Establish a national standard and timeline for industry to transition from "petrochemical-based dyes" to natural alternatives, such as calcium phosphate, Galdieria extract blue, gardenia blue, and butterfly pea flower extract
- Revoke the authorization of Citrus Red No. 2 and Orange B, two of the eight color additives listed under Subpart A of 21 C.F.R. Part 74
- Work with industry to eliminate — by the end of 2026 — the other six color additives listed under 21 C.F.R. Part 74, which include FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1., and FD&C Blue No. 2
- Authorize calcium phosphate, Galdieria extract blue, gardenia blue, and butterfly pea flower extract for use as color additives in food
- Partner with the National Institutes of Health (NIH) to conduct comprehensive research on how food additives impact children's health and development
- Request that food companies remove FD&C Red No. 3 sooner than the 2027-2028 deadline that FDA established when it granted a food additive petition in January 2025 to repeal the color additive regulations permitting the use of FD&C Red No. 3 in foods and in ingested drugs

Legal Framework

The Federal Food, Drug, and Cosmetic Act (FDCA) defines a color additive as a dye, pigment, or other substance that is capable of imparting color to food.[3] Unlike food substances, color additives cannot be introduced into the food supply based on a manufacturer's independent conclusion that the substance is Generally Recognized as Safe (GRAS).[4] As we discuss in more detail in this Client Alert, manufacturers frequently introduce ingredients into their food products through the GRAS self-affirmation pathway. Instead, Section 721 of the FDCA states that substances may only be used as a color additive in food if 1) FDA has issued a regulation listing such color additive, (2) the regulation authorizes the color additive for a specific use, and (3) the color additive and its use conform to the authorized use.[5]

FDA must also certify batches of certain color additives under the process set forth in its regulations in 21 C.F.R. Part 80, unless it has exempted the color additive from these certification requirements.[6] Color additives listed in 21 C.F.R. Part 73 are exempt from the requirements for batch certification, while all batches of color additives listed in 21 C.F.R. Part 74 must be certified. As noted above, the synthetic dyes that FDA intends to phase out of the nation's food supply are all listed in 21 C.F.R Part 74 and are therefore subject to batch certification.[7]

Potential Legal Obstacles

The announcement does not offer a legal basis for FDA to enforce some of the announced phase-out measures, including its plan to establish a timeline for industry's transition to natural alternatives and phase out of the most widely used certified color additives. The two color additives for which FDA indicated plans to revoke authorizations have very limited uses — Citrus Red No. 2 may be used only for coloring the skins of oranges, and Orange B may be used only for coloring the casings or surfaces of frankfurters and sausages. Therefore, to the extent FDA does not anticipate receiving any significant adverse comment, it may issue a direct-to-final rule to revoke the regulations authorizing these color additives.[8]

But revoking the regulations authorizing the other six color additives that are much more commonly used raises more complicated legal questions for FDA. Without the ability to avail itself of the streamlined, direct-to-final rulemaking process, FDA should expect to engage with industry through a rulemaking initiated either by FDA or upon request of an interested party requesting that FDA repeal a regulation prescribing the conditions under which a color additive may be safely used through the citizen petition process.[9] In January 2025, FDA granted such a color additive petition and revoked its regulations permitting the use of Red No. 3, a color additive ubiquitous in the food supply.[10] FDA concluded that, based on the scientific evidence cited in the petition and other relevant data, FD&C Red No. 3 can "induce cancer in male rats, through a rat specific hormonal mechanism," triggering the application of the Delaney Clause under Section 721(b)(5)(B) of the FDCA.[11] The Delaney Clause deems a color additive unsafe for food if FDA concludes that ingestion of the additive induces cancer in man or animal.[12]

FDA could grant similar citizen petitions to revoke the authorization of the other six color additives identified in the announcement. However, granting any such petition will require adequate and robust scientific evidence to survive judicial scrutiny.[13] FDA has explained that granting a petition that seeks repeal of a color additive regulation based upon new data on the safety of the color additive must be "adequate for FDA to conclude that there is no longer a reasonable certainty of harm for the intended use of the color additive or that it must be deemed unsafe under the Delaney Clause."[14]

The citizen petition is not a legal pre-requisite to action, however. FDA can act unilaterally to modify its rulemakings for certified color additives, but opponents of such activity will surely focus both on the administrative process employed to modify the rulemakings and the science used to justify such actions. Former FDA Commissioner Robert Califf acknowledged these legal obstacles in a December 2024 Senate hearing, stating that if they ban a synthetic food dye "it will go to court . . . [i]f we do not have the scientific evidence to support its ban, we will lose in court."[15]

Regardless of the path forward, FDA will need to navigate the legal obstacles that revoking the authorization of color additive regulations poses. As just one example, under 21 C.F.R. § 12.20 and § 12.22, regulated entities have 30 days to object to FDA's decision to revoke a regulation, and they may request a hearing with the agency regarding the revocation. Indeed, such a notice has already been filed regarding FDA's decision to revoke its regulations authorizing the use of Red No. 3 in foods and ingested drugs.[16] The Administrative Procedure Act (APA) also poses additional legal hurdles for FDA to overcome. These obstacles contextualize FDA's intent to cooperate with industry to voluntarily implement these new measures. Commissioner Makary specified that FDA will start in a "friendly way and see if we can do this without any statutory or regulatory changes, but we are exploring every tool in the toolbox to make sure this gets done very quickly."[17]

Conclusion

The announcement outlined FDA's anticipated reform of the use of color additives in the nation's food supply which includes revoking the authorization of several color additives, facilitating market access to more natural alternatives, and plans to post information about every food additive on an open-source website intended to be accessible to consumers at the point of sale.

Latham will continue to monitor for additional updates on these plans and the other announced measures, including whether FDA requires batch certification for the natural alternative color additives it intends to authorize in the coming weeks.

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Endnotes

[1] FDA News Release, *HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation's Food Supply* (Apr. 22, 2025), https://www.fda.gov/news-events/press-announcements/hhs-fda-phase-out-petroleum-based-synthetic-dyes-nations-food-supply (FDA News Release); US Department of Health and Human Services, *HHS/FDA Hold Press Event on Intent to Remove Food Dyes* (Apr. 22, 2025), https://www.youtube.com/watch?v=9A3hAR2mBPg&t=864s (Live Announcement).

[2] Live Announcement at 46:47.

[3] 21 U.S.C. § 321(t).

[4] 21 U.S.C. § 379e(a).

[5] 21 U.S.C. § 379e(a)(1)(A).

[6] *Id.* § 379e(a)(1)(B).

[7] *See* 21 C.F.R. Part 74, Subpart A (listing FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, Orange B., Citrus Red No. 2, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6).

[8] 21 C.F.R. §§ 74.250, 74.302

[9] 21 U.S.C. § 379e(d).

[10] Color Additive Petition From Center for Science in the Public Interest, et al.; Request To Revoke Color Additive Listing for Use of FD&C Red No. 3 in Food and Ingested Drugs, 90 Fed. Reg. 4628 (Jan. 16, 2025).

[11] *Id.* at 4631-32.

[12] 21 U.S.C. § 379e(b)(5)(B)(i).

[13] *See* 90 Fed. Reg. 4630 ("For FDA to grant a petition that seeks repeal of a color additive regulation based upon new data concerning the safety of the color additive, such data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm for the intended use of the color additive or that it must be deemed unsafe under the Delaney Clause.").

[14] *Id.*

[15] FDA Commissioner Robert Califf Testifies Before Senate Help Committee on Combating Diabetes, Obesity, https://www.youtube.com/watch?v=5upGvDdCZyM, at 29:50.

[16] Request for Hearing from Buchanan Ingersoll & Rooney PC, Docket No. FDA 2023-N-0437-34793, available at https://www.regulations.gov/document/FDA-2023-N-0437-34793.

[17] *Id.* at 1:04:33.