HAYNES BOONE

January 16, 2024

Citing No Risk to Humans, FDA Revokes Authorization of Color Additive Red No. 3[1]

By: Luke Nguyen and Suzie Trigg

Are duller candies headed to Americans in the next two years? Many consumers already try to avoid Red No. 3 food dye. Now, FDA has revoked authorization for the use of Red No. 3 as a color additive in food, dietary supplements, and ingested drugs. FDA took this step in response to a color additive petition submitted in late 2022 by the Center for Science in the Public Interest (CSPI) and several other consumer advocacy groups. Red No. 3 is often used to give candy, cakes, cupcakes, frozen desserts, frostings, and icings a bright red hue. FDA's revocation follows widespread criticism of its slow action regarding the color additive, California's ban of Red No. 3, other state proposals to ban the color additive, and criticism from Congress.

Why did FDA revoke authorization of Red No. 3?

Red No. 3 (erythrosine) is a color additive common to foods and certain ingested drugs. Outside of the United States, Red No. 3 is banned in Australia and New Zealand, and heavily regulated in Europe. In 2022, several advocacy groups filed a petition with FDA that requested revocation of Red No. 3's color additive authorization due to safety concerns. The petition cited studies linking Red No. 3 with an increased cancer risk in rats.[2]

Under the Food, Drug, and Cosmetic Act (FD&C Act), all color additives used in food and drugs are deemed unsafe unless the additive's use is approved by FDA.[3] Under the 1960 Delaney Clause, FDA must deem a color additive unsafe, as a matter of law, if it "induce[s] cancer when ingested by man or animal."[4]

After reviewing the petition and current scientific research, FDA determined that the color additive must be revoked because of its effect on male rats.[5] FDA explained that, while FDA believes that the risk of humans developing cancer from current exposure levels of Red No. 3 is low, the color additive is unsafe "as a matter of law" under the Delaney Clause. [6] FDA's commentary in connection with the revocation of the authorization of Red No. 3 does not address other concerns that consumer advocacy groups and others have raised over the past several years, such as its alleged association with attention deficit hyperactivity disorder (ADHD) in children.

Who is affected by the revocation?

All manufacturers and importers of food, dietary supplements, and ingested drugs using Red No. 3 must remove the color additive from products by the compliance deadline.

What happens if industry objects to FDA's revocation of authorization for Red No. 3?

FDA's rationale for revoking authorization for Red No. 3 is essentially that the Delaney Clause leaves the Agency no other option – not that the Agency has safety concerns. Those that object to the revocation must

[1] Prepared by Suzie Trigg and Luke Nguyen as of January 16, 2025.
[2] 88 Fed. Reg. 10245 (Feb. 17, 2023).
[3] 21 U.S.C. § 379(e)(a)(1).
[4] 21 U.S.C. § 379(e)(b)(5)(B)(i).
[5] 90 Fed. Reg. 4628, 4631 (January 16, 2025) (Revoking 21 CFR § 74.303).
[6] *Id.* at 4633.

file an objection or request for a hearing by February 18, 2025.[7] Upon filing of an objection or request for a hearing, the provision that is objected to is automatically stayed until final action on the filing is taken.[8]

For example, in 2018, FDA revoked authorization for seven food additives under the Delaney Clause.[9] The revocation received 50 comments, but only one purported to raise an objection.[10] The objection took issue with FDA's failure to establish "zero tolerances" for the food additives, as requested in the food additive petition, calling such failure "an arbitrary and unlawful failure to protect the safety of food."[11] However, since the "zero tolerance" portion of the petition did not propose the issuance of a new regulation, or the amendment or repeal of an existing regulation, it was not "the proper subject of a food additive petition."[12] Since the attempted objection was improperly raised, the original effective date was confirmed.[13]

Also in 2018, FDA repealed authorization for the use of lead acetate as a color additive in hair products.[14] Such revocation occurred because there was "no longer a reasonable certainty that no harm would result" from the use of lead acetate.[15] The final rule received several proper objections from Combe, Inc., which resulted in an administrative stay of the revocation until FDA responded to the objections.[16] It took FDA nearly four years to respond, causing a significant delay of the revocation's effective date.[17]

If FDA's revocation of Red No. 3 faces proper, timely objections, a delay in the effective date is possible, contingent upon the speed at which FDA responds to the objections. That said, given the widespread attention to and criticism of Red No. 3, as well as the California prohibition set to take effect in 2027, impacted stakeholders will want to consider whether reformulation is a more worthwhile investment.

When is compliance required?

Assuming there are no delays, food and dietary supplement manufacturers must remove all Red No. 3 from their products by **January 15, 2027**.

Assuming there are no delays, drug manufacturers must remove all Red No. 3 from their ingested drugs by **January 18, 2028**.

What enforcement actions may FDA take under the revocation, once effective?

A product that uses an unauthorized color additive would be adulterated under the FD&C Act.[18] FDA may take enforcement actions against manufacturers using unauthorized color additives, including warning letters, product seizures, mandatory recalls, and import refusals.

It is important to note that all certificates for existing batches and portions of batches of Red No. 3 will cease to be effective ***on the respective effective date listed in the revocation.*** Thus, for food, any lots of Red No. 3 will be considered "uncertified" on January 15, 2027. For ingested drugs, any lots of Red No. 3 will be

[7] 90 Fed. Reg. 4628 at 4629.
[8] 21 U.S.C. § 371(e)(2).
[9] *See* 85 Fed. Reg. 5555 (Jan. 1, 2020).
[10] *Id.* at 5556.
[11] *Id.*
[12] *Id.* at 5557.
[13] *Id.*
[14] 86 Fed. Reg. 56183 (Oct. 8, 2021).
[15] 83 Fed. Reg. 54665, 54671 (Oct. 31, 2018).
[16] 86 Fed. Reg. 56183 at 56185.
[17] *Compare* 83 Fed. Reg. 54665 (Oct. 31, 2018) *with* 86 Fed. Reg. 56183 (Oct. 8, 2021) (The original effective date was December 3, 2018, but the effective date after responding to the objections was January 6, 2022.).
[18] *See* 21 U.S.C. § 342(c)(1); 21 U.S.C. § 342(a)(4)(A).

considered “uncertified” on January 18, 2028. When Red No. 3 has been used in food or ingested drugs while its certificate is still effective (*i.e.* before the relevant effective date), the resulting products are not adulterated.[19]

What’s Next?

Food and drug manufacturers and importers should begin phasing out Red No. 3 to ensure timely compliance with the revocation and California law. While FDA leadership changes will take place in the coming weeks, it is unlikely the new administration will disturb the revocation. We will continue to closely monitor developments with Red No. 3 as the deadline for objections approaches and provide additional analysis as needed.provide additional analysis as needed.

[19] 90 Fed. Reg. 4628 at 4633.