



In Waning Days of the Current Administration, FDA Announces Red No. 3 Ban

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On January 15, 2025, FDA announced an order revoking the listings providing for the use of the color additive FD&C Red No. 3 in both foods (including dietary supplements) and ingested drugs. The order is in response to a 2022 petition filed by the Center for Science in the Public Interest, among other food safety and health advocates, which asserted that the additive induces cancer in male rats and urged the agency to revoke authorization.

FD&C Red No. 3 (also referred to as erythrosine) was first listed in 1907 under the provisions of the Food and Drugs Act of 1906 (Food Inspection Decision 76), and later provisionally listed in 1960 as Red No. 3 for food, drug and cosmetic use.¹ In 1969, FD&C Red No. 3 was permanently listed for use in food and ingested drugs and codified in §§74.303 and 74.1303. In 1990, the agency declined to extend the provisional listing of the additive for use in cosmetics and externally applied drugs based on evidence of thyroid neoplasia in rat carcinogenicity studies. However, the decision did not revoke the existing 1969 permanent listing for food and ingested drugs.

In the order, FDA states that based on the available data and information, the FD&C Red No. 3-induced thyroid tumors found in rats are “of limited relevance to humans.” However, citing section 721(b)(5)(B) of the Food, Drug and Cosmetic Act (the FD&C Act), often referred to as the Delaney Clause, the agency concluded that the findings of carcinogenicity render the color additive “unsafe” as a matter of law, regardless of the extent to which the experimental condition of the animal studies provides insight into the health effects of human consumption.²

The order further sets forth an effective date of **January 15, 2027**, for food and **January 18, 2028**, for ingested drugs. Subject to any forthcoming challenges to the order, the food industry and drug industry will need to move fairly quickly to assess potential formulation changes in advance of the respective effective dates.

¹ See 25 Fed. Reg. 9759, (October 12, 1960).

² See Section 721(b)(5)(B) of the FD&C Act (stating that a color additive shall be deemed unsafe for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.)

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