FDA to Revoke Authorization for the Use of Red No. 3 in Food and Ingested Drugs

Constituent Update

January 15, 2025

The FDA is revoking the authorization for the use of FD&C Red No. 3 as a matter of law, based on the Delaney Clause (/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act). The FDA is amending its color additive regulations (https://www.federalregister.gov/public-inspection/2025-00830/petition-color-additive-center-for-science-in-the-public-interest-et-al-request-to-revoke-color) to no longer allow for the use of FD&C Red No. 3 in food and ingested drugs in response to a 2022 color additive petition (https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FAP-CAP&id=CAP_3C0323&sort=Petition_Type_Number&order=ASC&startrow=1&type=basic&search=red). The petition requested the agency review whether the Delaney Clause applied and cited, among other data and information, two studies that showed cancer in laboratory male rats exposed to high levels of FD&C Red No. 3 due to a rat specific hormonal mechanism. The way that FD&C Red No. 3 causes cancer in male rats does not occur in humans. Relevant exposure levels to FD&C Red No. 3 for humans are typically much lower than those that cause the effects shown in male rats. Studies in other animals and in humans did not show these effects; claims that the use of FD&C Red No. 3 in food and in ingested drugs puts people at risk are not supported by the available scientific information.

The Delaney Clause, enacted in 1960 as part of the Color Additives Amendment to the FD&C Act, prohibits FDA authorization of a food additive or color additive if it has been found to induce cancer in humans or animals. This is not the first time the agency revoked an authorization based on the Delaney Clause. For example, in 2018, the FDA revoked the authorization for certain synthetic flavors (/food/hfp-constituent-updates/fda-removes-7-synthetic-flavoring-substances-food-additives-list) based on the Delaney Clause in response to a food additive petition.

FD&C Red No. 3 is a synthetic food dye that gives foods and drinks a bright, cherry-red color. The FDA estimates that FD&C Red No. 3 is not as widely used in food and drugs when compared to other certified colors (/food/food-ingredients-packaging/color-additives-information-consumers) based on information available in third-party food product labeling databases, food manufacturers' websites and other public information, and the FDA's certification data. FD&C Red No. 3 has been primarily used in certain food products, such as candy, cakes and cupcakes, cookies, frozen desserts, and frostings and icings, as well as certain ingested drugs.

Manufacturers who use FD&C Red No. 3 in food and ingested drugs will have until January 15, 2027 or January 18, 2028, respectively, to reformulate their products. Other countries still currently allow for certain uses of FD&C Red No. 3 (called erythrosine in other countries). However, foods imported to the U.S. must comply with U.S. requirements.

Additional Information

- Federal Register Notice (https://www.federalregister.gov/public-inspection/2025-00830/petition-color-additive-center-for-science-in-the-public-interest-et-al-request-to-revoke-color)
- FD&C Red No. 3 (/industry/color-additives/fdc-red-no-3)
- Food Chemical Safety (/food/food-ingredients-packaging/food-chemical-safety)
- Color Additives Information for Consumers (/food/food-ingredients-packaging/color-additives-information-consumers)
- Part III: Drugs and Foods Under the 1938 Act and Its Amendments (/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments)