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FDA Revoking Authorization for Use of Red No. 3 in Food and Ingested Drugs

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On January 15, 2025, the Food and Drug Administration (FDA) amended its color additive regulations by revoking its authorization for use in food and ingested medications of [FD&C Red No. 3 \(Red No. 3\)](#), a synthetic red dye. This decision is based on the Delaney Clause of the Federal Food, Drug and Cosmetic Act (FD&C Act), which prohibits FDA authorization of any food or color additive that causes cancer in humans *or animals*.

The FDA's revocation comes about in response to a 2022 petition filed by advocacy groups, including the Center for Science in the Public Interest (CSPI), citing two studies in which male laboratory rats exposed to high levels of Red No. 3 developed thyroid cancer. FDA had maintained the approval of the dye in food on the basis that the hormonal mechanism for such cancer growth does not occur in humans and the exposure amount of Red No. 3 required to cause cancer in rats is much higher than the typical exposure level of the average human. The petitioners urged the ban on the basis that the language of the Delaney Clause precludes the approval of any food or color additive that is shown to cause cancer in humans ***or animals*** rendering moot the argument about the mechanism.

Food manufacturers will have until January 15, 2027, to phase out the use of Red No.3, while manufacturers of ingested drugs have until January 18, 2028. The FDA had previously disallowed the dye in non-oral medications and cosmetics. California had already banned Red No. 3 in food, and some 10 other states have had bans in process. The dye also has been banned or restricted in other countries, including the European Union, Australia and Japan.

If you have questions about the FDA action or need guidance regarding a product that may be affected, please contact Foster Garvey's [Food & Beverage](#) team.

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