

The Virgin Islands Consortium

FDA Bans Red Dye No. 3 in Food and Medications

Manufacturers must remove the synthetic dye by 2027 for food and 2028 for drugs, following studies linking it to cancer in animals. The dye is commonly found in candies, cakes, frostings, and strawberry-flavored desserts.

Health / **Published On January 17, 2025 05:23 AM /**

Staff Consortium **January 17, 2025**



The U.S. Food and Drug Administration (FDA) has announced a ban on FD&C Red No. 3, a synthetic dye commonly used in candies, cakes, frostings, and strawberry-flavored desserts, as well as in certain medications and dietary supplements. The decision requires manufacturers to phase out the dye by January 15, 2027, for food products, and January 18, 2028, for ingested drugs.

The ban is based on the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, which prohibits the use of additives shown to cause cancer in humans or animals. While studies indicate that high doses of FD&C Red No. 3 caused cancer in male rats, the FDA noted that these effects do not occur in humans at typical exposure levels.

FD&C Red No. 3, known for its bright cherry-red color, is used in a variety of foods, including candies, cakes, frostings, frozen desserts, and strawberry-flavored treats. The dye is also present in some oral medications and dietary supplements. A search of the U.S. Department of Agriculture's Branded Foods Database identified 9,201 food products containing Red No. 3, underscoring its widespread use.

The Delaney Clause prohibits the FDA from authorizing additives found to induce cancer in humans or animals, regardless of the relevance of the findings to human health. While the cancer observed in male rats was caused by a rat-specific hormonal mechanism that does not occur in humans, the clause necessitates a ban on the dye. Other studies, including those involving humans and other animals, showed no similar effects.

Consumers can check ingredient labels to determine whether FD&C Red No. 3 is present. It may be listed under the following names:

- FD&C Red No. 3
- FD&C Red 3
- Red 3

The dye has been used in foods such as maraschino cherries, fruit cocktails, ice pops, and seasonal candies like candy corn. It can also be found in medications such as acetaminophen (pain reliever), fluoxetine (antidepressant), gabapentin (anticonvulsant), and omeprazole (heartburn treatment). However, its use in cosmetics and topical drugs was banned in 1990.

The FDA emphasized that typical human exposure to FD&C Red No. 3 is far lower than the levels tested in animal studies. Nevertheless, the agency is bound by the Delaney Clause to revoke its authorization. Manufacturers of affected products are required to reformulate their offerings within the specified timelines to comply with U.S. regulations. Foods imported into the country must also adhere to these standards, even though other nations, where the dye is known as erythrosine, continue to allow its use.

This decision follows the FDA's broader commitment to ensuring consumer safety and transparency in food and drug products. The agency encourages consumers to remain informed by reviewing product labels and making choices aligned with their preferences.