



FDA Bans Red Dye 3 in Foods and Drugs Over Cancer Concerns

On Wednesday, the U.S. Food and Drug Administration (FDA) banned the use of Red Dye 3, also known as Red 3 and officially known as FD&C Red No. 3, in food and ingested drugs over the risks of cancer in humans and animals. The dye, originally approved for use in 1907, has remained a staple in processed foods and products for over a century, despite mounting health concerns. In 1990, the FDA prohibited its use in cosmetics and topical drugs due to evidence linking it to cancer.

The FDA <u>outlined</u> a timeline for the phaseout of the dye, stating,

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.



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The agency noted that consumers might still find the dye in products after the deadline, as those items could have been manufactured earlier.

The Petition

The FDA's ban on FD&C Red No. 3 stems from a 2022 petition by the Center for Science in the Public Interest (CSPI) and 23 other organizations. The petition called on the FDA to revoke Red 3's approval for use in foods, dietary supplements, and oral drugs. It cited the Delaney Clause, which bans additives linked to cancer, and highlighted decades-old studies demonstrating that Red 3 causes thyroid tumors in animals.

"If the data were strong enough to ban Red 3 in cosmetics 30 years ago, they're surely strong enough to ban it today in foods and drugs," said CSPI President Dr. Peter Lurie in the <u>press release</u> on the petition.

The petitioners noted that despite evidence of health risks, Red 3 remains widespread in candies like Nerds, Peeps, and SweeTarts. Non-candy items like Betty Crocker's mashed potatoes and PediaSure shakes for children also contain the dye.

The coalition also highlighted the dye's presence in ADHD medication Vyvanse, noting its link to behavioral issues.

"The primary purpose of food dyes is generally to make junk food look more attractive, especially to kids, or to trick their parents into thinking a food contains a healthy fruit like strawberries," said Lurie.



Written by **Veronika Kyrylenko** on January 16, 2025



"When the purpose is purely cosmetic, why is any level of risk acceptable?"

FDA's Inconsistency

The FDA's decision to ban Red 3 has raised questions about the agency's consistency in addressing the dye's risks. While citing the Delaney Clause, the FDA simultaneously downplayed the dye's danger to human health.

In its official statement, the FDA acknowledged that studies have demonstrated cancer in male rats exposed to high levels of Red 3. Yet, it stressed that "the way that FD&C Red No. 3 causes cancer in male rats does not occur in humans." The agency further noted, "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." It concluded that "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."

Petitioners Respond to the Ban

The petitioners behind the 2022 push to ban Red 3 <u>welcomed</u> the FDA's decision, but highlighted the agency's long delay in addressing the dye's risks. "At long last, the FDA is ending the regulatory paradox of Red 3 being illegal for use in lipstick but perfectly legal to feed to children in the form of candy," said Lurie.

The organization also criticized the FDA's historical inaction. "Congress made plain decades ago that this was exactly the type of chemical — one that causes cancer in animals — it was trying to keep out of the U.S. food supply," Lurie stated.

And critics took issue with the FDA's minimization of the risks. Lurie noted:

We're not surprised FDA has asserted that the risk is small, since it's a chemical they failed to ban for years.

CSPI urged parents to avoid <u>all synthetic dyes</u>, such as Yellow 5 and Red 40, due to growing evidence of their impact on children's behavior. The group also called for broader reforms to strengthen the FDA's post-market chemical safety assessments, pointing to other concerning additives like titanium dioxide and aspartame. "If the incoming administration wants to protect children's health, it should require companies to warn parents of the risks that all synthetic dyes pose to their children — right on the label." Lurie added.

The FDA currently allows the use of eight synthetic dyes: Blue No. 1, Blue No. 2, Green No. 3, Orange B, Red 40, Yellow 5, Yellow 6, and Citrus Red.

Prospective HHS Secretary

Donald Trump's nominee for Secretary of Health and Human Services (HHS), Robert F. Kennedy Jr., has been a vocal advocate for <u>food safety</u>. Through his nonprofit organization Children's Health Defense, Kennedy has actively held federal agencies accountable for their regulation of drugs and food while informing the public of the regulatory oversight and health risks of various environmental exposures.

In a viral clip posted last year, Kennedy made a direct connection between the use of synthetic dyes and America's lower life expectancy compared to countries that banned the dyes. He further argued that synthetic dyes contribute to chronic diseases. Those include cancer, obesity, diabetes, kidney disease,



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Alzheimer's, and other conditions that disproportionately affect Americans.

Kennedy said in a clip,

Restaurants that serve contaminated food are fined or shut down. But when it's the government that approves the poisons in our food, a few people get very, very rich, and the toxins end up in every supermarket aisle.

"The first thing I'd do [as HHS secretary] isn't going to cost you anything because I'm just gonna tell the cereal companies: Take all the dyes out of their food," Kennedy <u>said</u> in October.

It must be remembered that both the HHS and the FDA, its subsidiary entity, are unconstitutional, as nowhere does the Constitution delegate to the federal government any authority to regulate food, drugs, or additives.

At the end of the day, safeguarding the health of individuals and their children from harmful chemicals ultimately rests with Americans themselves. While this responsibility may not always be straightforward, it cannot be ignored. Taking the time to read ingredient labels and make informed decisions demands effort — but is a vital step toward building a safer, healthier future.





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