FDA Bans Red Dye No. 3 in Food and Drugs, Citing Cancer Risks

Key Takeaways

- The FDA's ban on FD&C Red No. 3 is rooted in the Delaney Clause, prohibiting carcinogenic additives in food and drugs.
- Red Dye No. 3, approved in 1907, faced scrutiny due to cancer risks in high doses, leading to its ban in cosmetics in 1990.
- Renewed advocacy and international actions prompted the FDA to align with global standards, banning the dye in food and drugs.
- Manufacturers must reformulate products containing Red No. 3, reflecting a broader shift towards consumer safety and regulatory scrutiny.

Studies shows that Red Dye No. 3 was associated with tumor growth in male rats.

On January 15, 2025, the FDA announced a ban on the use of FD&C Red No. 3, also known as Red Dye No. 3 or erythrosine, in food and ingested drugs. This synthetic dye, used to give these products a vibrant red hue, will be phased out entirely by January 15, 2027, for food products and January 18, 2028, for ingested drugs.[1]

Red Dye No. 3, Cancer Risks, Oncology

The decision, rooted in the Delaney Clause of the Federal Food, Drug, and Cosmetic Act, is a culmination of decades of debate, and prohibits the FDA from authorizing additives found to induce cancer in humans or animals. The ban signifies a long-overdue shift toward prioritizing consumer safety and underscores the ongoing need for vigilance in evaluating food and drug additives.[1]

Red Dye No. 3 was first approved for food use in 1907 and became a staple in products ranging from candy to drugs. While Red Dye No. 3 has been deemed safe for human consumption at current levels, studies in male rats revealed a cancer risk associated with high doses of the dye. The FDA responded by banning its use in cosmetics in 1990 but stopped short of taking similar action for food and drugs, citing resource constraints.[2,3]

Renewed advocacy, including a 2022 petition by the Center for Science in the Public Interest (CSPI), reignited calls for a complete ban. The CSPI argued that the dye's continued use posed unnecessary health risks and highlighted its presence in more than 9200 products.[1,4]

The FDA's move aligns with actions taken by other countries, including Australia, Japan, and European Union member states, where Red Dye No. 3 has been banned or severely restricted. It also reflects a broader shift in

public sentiment and regulatory scrutiny of artificial additives. Manufacturers have been given a multi-year transition period to reformulate products containing FD&C Red No. 3. Companies in the food and pharmaceutical sectors will need to identify and implement alternatives while ensuring compliance with FDA regulations.[1,2]

"Revoking the authorized use of Red No. 3 is an example of the FDA using its risk and science-based authority to review the safety of products in the marketplace," said Sarah Gallo, senior vice president of product policy and federal, in a written statement via email. "Food and beverage companies will continue to follow the latest science and comply with all food safety regulations to ensure safe and available choices for consumers."[5]

By addressing the potential cancer risks associated with this dye, the FDA is taking a crucial step toward ensuring that medications are free from unnecessary and harmful additives. This move underscores the importance of ongoing vigilance in evaluating the safety of substances used in pharmaceuticals, with lasting implications for public health and regulatory practices moving forward.

REFERENCES

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