

LEGAL UPDATES

PUBLISHED: JANUARY 16, 2025

## Service

FDA Regulatory

## Industries

Food Systems

Life Sciences

## Professionals

SETH A. MAILHOT

WASHINGTON:

202.378.2306

SETH.MAILHOT@

HUSCHBLACKWELL.COM

EMILY LOFTIS

WASHINGTON:

202.378.9313

EMILY.LOFTIS@

HUSCHBLACKWELL.COM

# FDA Bans the Use of Red No. 3 in Food and Ingested Drugs

On January 16, the U.S. Food and Drug Administration (FDA) announced that it is revoking the authorization for use of FD&C Red No. 3 in food (including dietary supplements) and ingested drugs. The dye is commonly used in beverages, candies, and other foods and drugs for its appealing red color.

The FDA has based its decision on the Delaney Clause, which prohibits the approval of any food or color additive found to induce cancer in humans or animals. In its announcement, the FDA recognized that Red No. 3 is not shown to cause cancer in humans, but the studies linking the dye to the development of cancer in rats are enough to require the ban under the Delaney Clause. The ban applies to domestic products as well as products manufactured abroad and imported into the United States.

Since the FDA received a petition to ban Red No. 3 for use in food in 2022, California passed legislation to prohibit the sale of foods with Red No. 3, and lawmakers in 10 other states introduced similar legislation.

This decision extends a previous ban from 1990 which prohibited the use of Red No. 3 in cosmetics and topical drugs. At that time, the FDA denied a petition for permanent authorization, citing data demonstrating that Red No. 3 caused cancer in rats. Use of Red No. 3 will now be prohibited in food, topical and ingested drugs, and cosmetics.

The deadline for manufacturers to reformulate products will be January 15, 2027 for food and January 18, 2028 for drugs.

## Contact us

We understand that regulatory changes can pose challenges, and we are here to support you through this transition. We will continue to monitor the agency's actions related to the use of dyes and additives in food, drugs, and

cosmetics. If you have any questions or require assistance, please do not hesitate to reach out to Seth Mailhot, Emily Loftis, or your Husch Blackwell attorney.