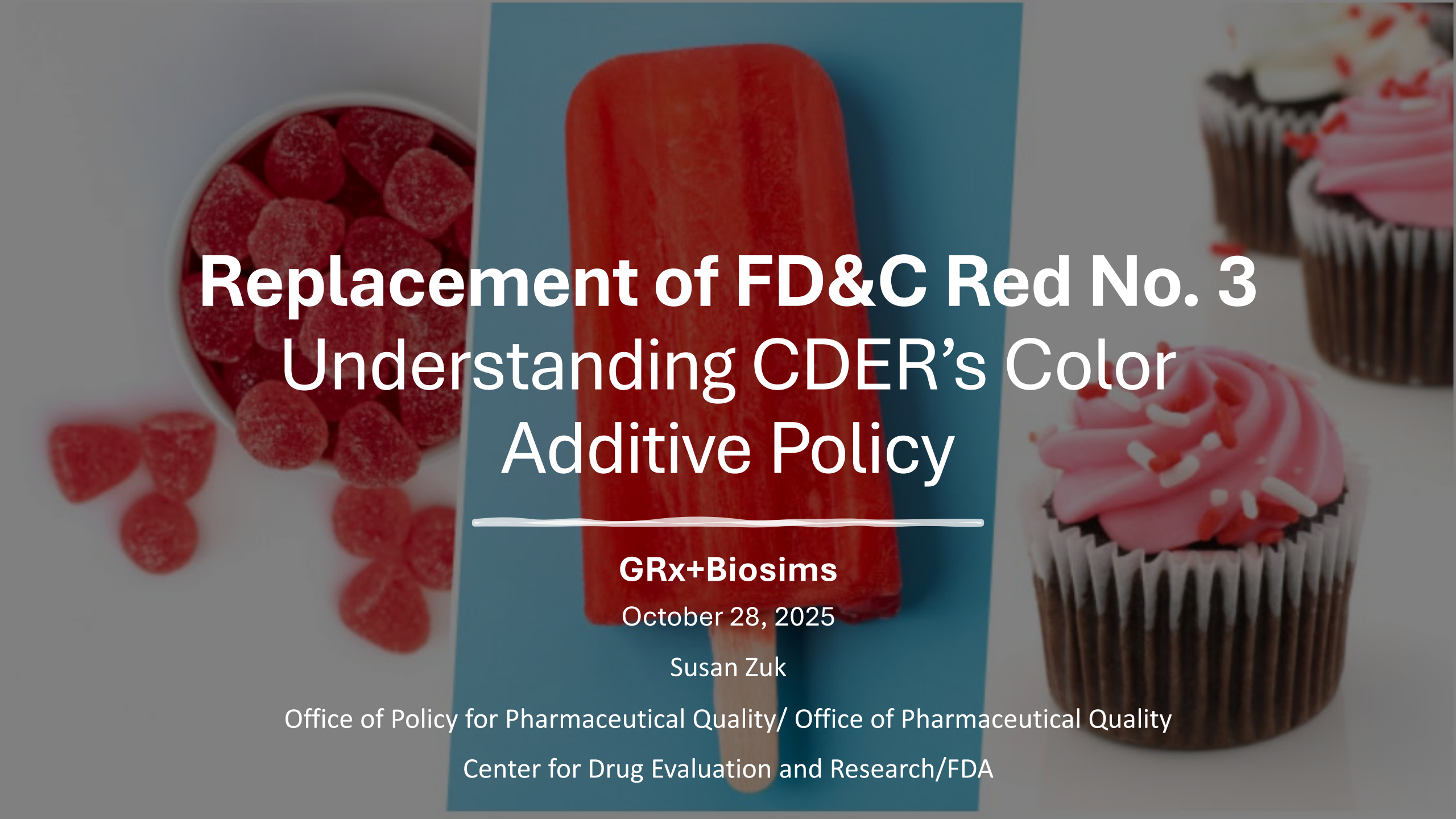


Replacement of FD&C Red No. 3
Understanding CDER's Color Additive Policy

GRx+Biosims

October 28, 2025

Susan Zuk

Office of Policy for Pharmaceutical Quality/ Office of Pharmaceutical Quality

Center for Drug Evaluation and Research/FDA

FD&C Red No. 3

- The FDA will no longer allow for the use of FD&C Red No. 3 in food and ingested drugs.
- On January 15, 2025, the FDA issued an order to revoke these authorizations. 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.

PART 74—Listing of Color Additives Subject to Certification

Regulations to be revoked

Subpart A - Foods

- § 74.303 FD&C Red No. 3.

  (c) ***Uses and restrictions*. FD&C Red No. 3 may be safely used for coloring foods generally (including dietary supplements)** in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

Subpart B - Drugs

- § 74.1303 FD&C Red No. 3.

  (b) ***Uses and restrictions*. FD&C Red No. 3 may be safely used for coloring ingested drugs i**n amounts consistent with good manufacturing practice.

ecfr.gov/current/title-21/part-74

What governs color additives in drugs?

Color additives used in drugs must be listed in and conform to FDA's color additive regulations.*

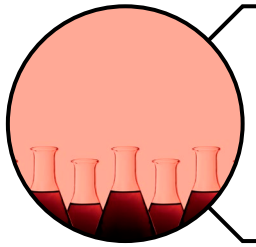
If FDA changes the color additive regulations (e.g., removing a color additive), drug products that no longer comply with the regulations must be updated to conform with the regulations.

If FDA removes a color additive from the regulations, any drug product containing that additive will be considered adulterated and cannot be marketed.

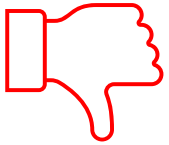
*The color additive regulations are found in 21 CFR parts 70-71, 73-74, and 80-82.

FD&C Red No. 3

Applicants and manufacturers must remove or replace FD&C Red No. 3 in drug products by January 18, 2028.



Products under development, new applications and reformulated products in supplements should not propose to use FD&C Red No. 3.

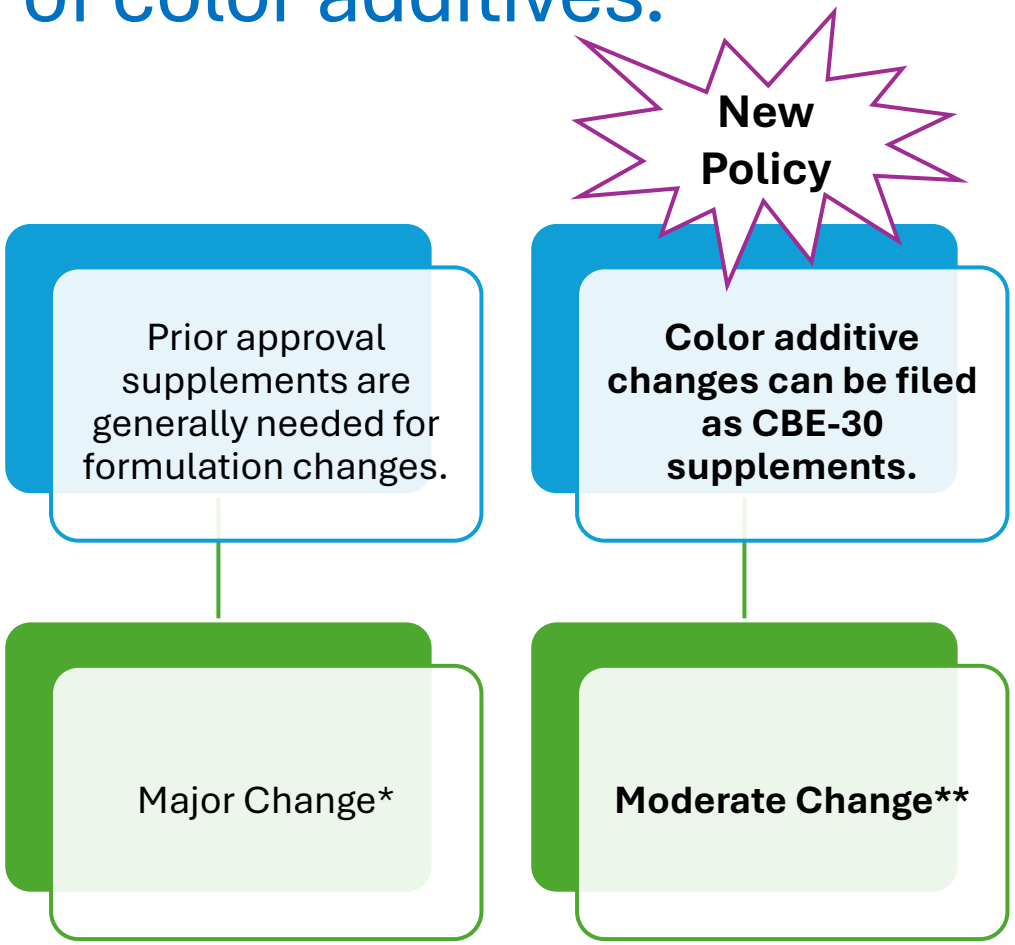


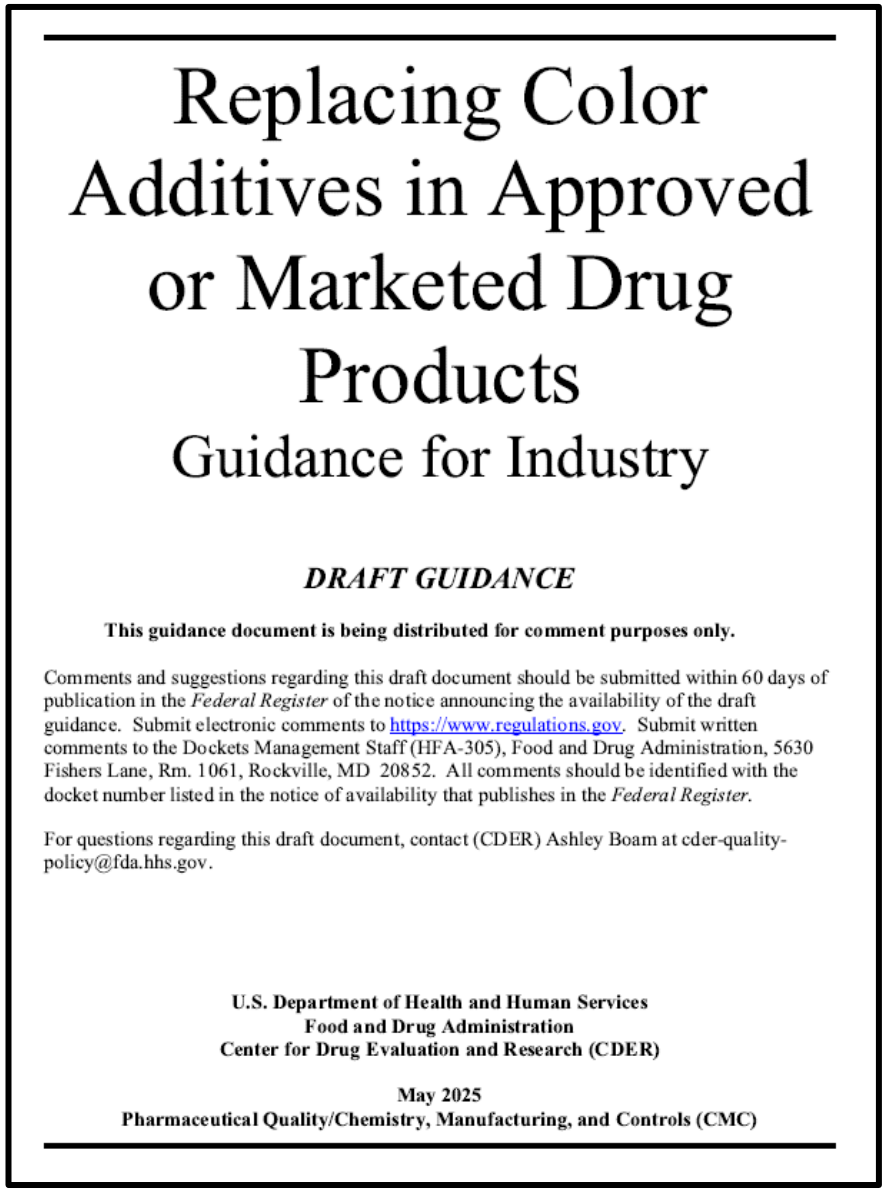
New submissions in which FD&C Red No. 3 is proposed for commercial marketing will not be approved.*

*See 21 CFR 314.127(a)(8)(i)(A)

Products such as OTC monograph drugs that are marketed without an application have the same deadline for removal or replacement of FD&C Red No. 3.

New guidance allows for expeditious replacement of color additives.





Replacing Color Additives in Approved or Marketed Drug Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Ashley Boam at cder-quality-policy@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2025
Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC)

*See § 314.70(b)(2)(i) and 21 CFR 314.97(a). **See § 314.70(c), Changes Being Effected in 30 days

Information to be provided* when replacing color additives in drugs

Manufacture one batch at pilot scale or larger

Perform pharmaceutical development studies and dissolution or in vitro release testing studies (as applicable)

Submit release test data and batch records

Provide 3 months of stability data at accelerated and long-term stability conditions at filing

Update and validate analytical methods, as appropriate.

* Manufacturers of OTC monograph drug products should retain the information described at the manufacturing facility.

Color Additives in the News

Kraft Heinz Commits to Eliminating Artificial Food Dyes by the End of 20

Company said it will not launch any new products in the U.S. with arti colors, starting today

By **Kevin Loria**
Senior Health & Food Reporter

June 17, 2025

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Consumer Reports June 17, 2025

FDA NEWS RELEASE

HHS, FDA to Phase Out Petroleum-Based Synthetic Dyes in Nation's Food Supply

For Immediate Release: April 22, 2025

The U.S. Department of Health and Human Services and U.S. Food and Drug Administration (FDA) today announced a series of new measures to phase out all petroleum-based synthetic dyes from the nation's food supply—a significant milestone in the administration's broader initiative to Make America Healthy Again.

Challenge Question:

Can the 4 new natural dyes FDA approved in 2025 be used in drugs?
How would you find out?

- 21 CFR 73.167 Galdieria extract blue, a blue color derived from the unicellular red algae Galdieria sulphuraria
- 21 CFR 73.69 Butterfly pea flower extract, a blue color that can be used to achieve a range of shades including bright blues, intense purple, and natural greens
- 21 CFR 73.80 Calcium phosphate, a white color
- 21 CFR 73.168 Gardenia (Genipin) Blue


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