HAYNES BOONE

As Promised, FDA Announces Approval of Three Color Additive Petitions[1]

In April 2025, the U.S. Food and Drug Administration (FDA) requested that food manufacturers phase out the use of specified food dyes. When FDA announced its plan to phase out certain food dyes, FDA also committed to expediting the approval of potential alternatives. On May 9, 2025, the FDA announced its imminent approval of three pending color additive petitions authorizing expanded uses of food colors derived from natural sources.

What Color Additive Petitions Did the FDA Approve?

The FDA has indicated that on May 12, 2025, the following color additive petitions will be approved:

Color	Intended Use	Petitioner and Date of Petition	Anticipated CFR
Butterfly pea flower extract (Blue)	Expansion of existing authorization to provide for the expanded safe use of butterfly pea flower extract as a color additive in ready-to-eat cereals, crackers, snack mixes, hard pretzels, plain potato chips (restructured or baked), and plain corn chips, tortilla chips, and multigrain chips at levels consistent with good manufacturing practice (GMP)	Sensient Colors, LLC December 5, 2023	Revised 21 CFR 73.29
Calcium phosphate (White)	New authorization to provide for the safe use of calcium phosphate as a color additive in ready-to-eat chicken products, white candy melts, doughnut sugar, and sugar for coated candies	Innophos, Inc. February 22, 2023	21 CFR 73.80
Galdieria Extract Blue	New authorization for the safe use of *galdieria* extract blue, derived from unicellular red algae (*Galdieria sulphuraria*), in various food categories at levels consistent with GMP	Fermentalg July 27, 2021	21 CFR 73.167

When May Industry Use the Color Additives?

The FDA has indicated that a Final Rule authorizing the use of each color additive will be dated May 12, 2025. New rules become effective 30 days after publication in the Federal Register. Food manufacturers should anticipate that they may begin using the new color additives in accordance with the approved uses as of the effective date of the Final Rule applicable to the color additive.

What Additional Considerations Apply to the Use of the Color Additives?

While the FDA has followed through on its commitment to expedite color additive authorizations, the recently announced authorizations are not blanket approvals of all uses. Instead, like all food additives and color additives, manufacturers must use the color additives only for the specific uses and in accordance with all restrictions outlined in the FDA's regulations.

[1] Prepared by Suzie Trigg as of May 9, 2025.

The additives must also meet any specifications set forth in the FDA's authorizing regulations. For example, the FDA's existing authorization for butterfly pea flower extract specifies that it must not have levels of lead, arsenic, mercury, or cadmium exceeding 1part per million (ppm). Ensuring consistent compliance with the FDA's specifications could mean the addition of a step for batch testing for heavy metals. Food manufacturers must work with suppliers to verify that the color additives provided meet the FDA's specifications and are sourced from approved natural sources and may need to implement or update supplier qualification procedures to ensure ongoing compliance.

The use of the new color additives triggers reformulation of existing products, which is seldom fast or straightforward. Existing products could only use the new color additives if the use would align with FDA's authorizations. Reformulation also necessitates labeling changes and sets of a possible cascade of other considerations, such as whether a new Global Tade Item Number (GTIN), which is the number encoded in a GS1 barcode, is needed.

Food manufacturers must also consider how the use of different color additives derived from natural sources impacts food safety programs and update food safety programs to address any new hazards. Putting the potential ripple effects into context, the clock is running quickly for manufacturers to plan how to meet the FDA's target date of the end of 2026 to phase out petroleum-based food dyes, as the successful marketing of a reformulated food that uses naturally derived alternatives could be a long journey.