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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2021-C-0925]

Listing of Color Additives Exempt From Certification; Galdieria Extract Blue; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 26, 2025, for the final order that appeared in the **Federal Register** of May 12, 2025. The final order amends the color additive regulations to provide for the safe use of galdieria extract blue as a color additive at levels consistent with good manufacturing practice (GMP) in: non-alcoholic beverages and beverage bases, fruit drinks, fruit smoothies, fruit juices, vegetable juices, dairy-based smoothies, milk shakes and flavored milks, yogurt drinks, milk-based meal replacement and nutritional beverages, breakfast cereal coatings, hard candy, soft candy and chewing gum, flavored frostings, ice cream and frozen dairy desserts, frozen fruits, water ices and popsicles, gelatin desserts, puddings and custards, whipped cream, yogurt, frozen or liquid creamers (including non-dairy alternatives), and whipped toppings (including non-dairy alternatives).

DATES: The effective date of June 26, 2025, for the final order published in the **Federal Register** of May 12, 2025 (90 FR 20104), is confirmed.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the

heading of this final order into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephanie A. Hice, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-348-1740 or Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 12, 2025 (90 FR 20104), we amended the color additive regulations to add § 73.167 (21 CFR 73.167) “Galdieria extract blue,” to provide for the safe use of galdieria extract blue as a color additive at levels consistent with GMP in: non-alcoholic beverages and beverage bases, fruit drinks, fruit smoothies, fruit juices, vegetable juices, dairy-based smoothies, milk shakes and flavored milks, yogurt drinks, milk-based meal replacement and nutritional beverages, breakfast cereal coatings, hard candy, soft candy and chewing gum, flavored frostings, ice cream and frozen dairy desserts, frozen fruits, water ices and popsicles, gelatin desserts, puddings and custards, whipped cream, yogurt, frozen or liquid creamers (including non-dairy alternatives), and whipped toppings (including non-dairy alternatives).

We gave interested persons until June 11, 2025, to file objections or requests for a hearing (90 FR 20104). We received no objections or requests for a hearing on the final order. Therefore, we find that the effective date of the final order that published in the **Federal Register** of May 12, 2025, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the May 12, 2025, final order. Accordingly, the

amendments issued thereby became effective June 26, 2025.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16046 Filed 8-20-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2023-C-0544]

Listing of Color Additives Exempt From Certification; Calcium Phosphate; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 26, 2025, for the final order that appeared in the **Federal Register** of May 12, 2025. The final order amends the color additive regulations 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.

DATES: The effective date of June 26, 2025, for the final order published in the **Federal Register** of May 12, 2025 (90 FR 20097) is confirmed.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final order into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rachel Morissette, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1278 or Barbara Little, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug

Administration, 5001 Campus Dr.,
College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 12, 2025 (90 FR 20097), we amended the color additive regulations to add § 73.80 (21 CFR 73.80) “Calcium phosphate,” 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.

We gave interested persons until June 11, 2025, to file objections or requests for a hearing. We explained that, to file an objection, a person must, among other things, specify with particularity the provision(s) of the regulation to which they object and the grounds for the objection (90 FR 20097 at 20100). Within each objection, persons also must specifically state whether they request a hearing. We received two general comments, one that did not address calcium phosphate or color additives and one that disagreed with the order, but the comments did not meet the requirements to be considered an objection under 21 CFR 12.22(a)(2) or (3). Therefore, we find that the effective date of the final order that published in the **Federal Register** of May 12, 2025, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the May 12, 2025, final order. Accordingly, the amendments issued thereby became effective June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16047 Filed 8-20-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2024-C-0971]

Listing of Color Additives Exempt From Certification; Butterfly Pea Flower Extract; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 26, 2025, for the final order that appeared in the **Federal Register** of May 12, 2025. The final order amends the color additive regulations to provide for the expanded safe use of butterfly pea flower extract as a color additive at levels consistent with good manufacturing practice (GMP) 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.

DATES: The effective date of June 26, 2025, for the final order published in the **Federal Register** of May 12, 2025 (90 FR 20101), is confirmed.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final order into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710 or Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 12, 2025 (90 FR 20101), we amended the color additive regulations at § 73.69 (21 CFR 73.69) “Butterfly pea flower extract,” to provide for the expanded safe use of butterfly pea flower extract as a color additive at levels consistent with GMP

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.

We gave interested persons until June 11, 2025 (90 FR 20101 at 20101) to file objections or requests for a hearing. We explained that, to file an objection, persons must, among other things, specify with particularity the provision(s) of the regulation to which they object and the grounds for the objection (Id. at 20103). Within each objection, persons also must specifically state whether they request a hearing (Id.). We received one comment about labeling of the color additive, but the comment did not meet the requirements to be considered an objection under 21 CFR 12.22(a)(2) or (3). Therefore, we find that the effective date of the final order that published in the **Federal Register** of May 12, 2025, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the May 12, 2025, final order. Accordingly, the amendments issued thereby became effective June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16045 Filed 8-20-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA-2025-N-2219]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Pharmacogenetic Assessment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the pharmacogenetic assessment system into class II (special