



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2026-C-8831]

Gardenia Blue Interest Group; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Gardenia Blue Interest Group (GBIG or petitioner), c/o Exponent, Inc., proposing that we amend our color additive regulations to expand the safe use of gardenia (genipin) blue in various foods at levels consistent with good manufacturing practice. The petition also proposes to lower the specification for arsenic in gardenia (genipin) blue.

DATES: The color additive petition was filed on August 4, 2026.

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 document 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.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 6C0343), submitted by GBIG, c/o Exponent, Inc., 1150 Connecticut Ave. N.W., Suite 1100, Washington, D.C. 20036. The petition proposes that we amend our color additive regulations in 21 CFR 73.168 (“Gardenia (genipin) blue”) to expand the safe use of

gardenia (genipin) blue to include use in: (1) sponge cake; (2) alcoholic mixed drinks; (3) carbonated drinks; (4) powdered beverages; (5) processed breakfast cereals; (6) chewing gum; (7) instant iced tea; (8) wasabi paste and powder; (9) sugar coating; (10) syrup for shaved ice; (11) icing; (12) creamers and whiteners; (13) ice cream and frozen dairy desserts; (14) frozen desserts (edible ices); (15) gelatin, puddings, custards, and pie filling; (16) jam, jellies, and marmalade; (17) flavored milk and both flavored and unflavored yogurt; (18) snack foods; (19) fruit preparation, syrup, and toppings; and (20) chewable tablets, at levels consistent with good manufacturing practice. The petition also proposes to lower the specification for arsenic in gardenia (genipin) blue from ≤ 2 mg/kg (ppm) to ≤ 1 mg/kg (ppm). FDA may also consider other changes to the regulation, as appropriate, during the course of our review.

The petitioner claims that this action is categorically excluded under 21 CFR 25.32(k) because granting this petition would authorize the use of a substance intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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