



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2021-C-0522]

#### 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), proposing that the color additive regulations be amended to provide for the safe use of gardenia blue powder in various foods.

**DATES:** The color additive petition was filed on April 20, 2021.

**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 Additive Safety (HFS-255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710; or Alexandra Jurewitz, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), we are giving notice that we have filed a color additive petition (CAP 1C0319), submitted by GBIG, c/o Exponent, Inc., 1150 Connecticut Avenue NW, Suite 1100, Washington, D.C. 20036. The petition proposes to amend the color

additive regulations in part 73 (21 CFR part 73, “Listing of Color Additives Exempt From Certification”) to provide for the safe use of gardenia blue powder as a color additive in: (1) sport drinks; (2) flavored or enhanced, noncarbonated water; (3) fruit drinks and ades; (4) ready-to-drink tea; (5) hard candy; and (6) soft candy, at levels consistent with good manufacturing practice.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is 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.

Dated: June 23, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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