



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

Listing of Color Additives Exempt from Certification; Gardenia (Genipin) 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 August 29, 2025, for the order that appeared in the *Federal Register* of July 15, 2025. The order amends the color additive regulations to provide for the safe use of gardenia (genipin) blue as a color additive, at levels consistent with good manufacturing practice (GMP), in sport drinks, flavored or enhanced non-carbonated water, fruit drinks and ades, ready-to-drink teas, hard candy, and soft candy.

DATES: The effective date of August 29, 2025, for the order published in the *Federal Register* of July 15, 2025 (90 FR 31586), 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, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710; or Keronica Richardson, 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 July 15, 2025 (90 FR 31586), we amended the color additive regulations to add § 73.168 (21 CFR 73.168) “Gardenia (genipin) blue,” to provide for the safe use of gardenia (genipin) blue at levels consistent with GMP in sport drinks, flavored or enhanced non-carbonated water, fruit drinks and ades, ready-to-drink teas, hard candy, and soft candy. In the *Federal Register* of August 6, 2025 (90 FR 37793), we published a correction to the order clarifying the appropriate specification for methanol and amending the codified language of the regulation.

We gave interested persons until August 14, 2025, to file objections or requests for a hearing (90 FR 31586 at 31587). We received no objections or requests for a hearing on the order. Therefore, we find that the effective date of the order that published in the *Federal Register* of July 15, 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 July 15, 2025, order. Accordingly, the amendments issued thereby became effective August 29, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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