4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

Fermentalg; 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 Fermentalg, proposing that the color additive regulations be amended to provide for the safe use of blue *Galdieria* extract, derived from unicellular red algae (*Galdieria sulphuraria*), as a color additive in various food categories at levels consistent with good manufacturing practice.

DATES: The color additive petition was filed on July 27, 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: Stephanie A. Hice, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-348-1740.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) 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 1C0320), submitted by Fermentalg, 4 Rue Rivière, 33500 Libourne, France. The petition proposes to amend the color additive regulations in part 73 (21 CFR 73), "Listing of Color Additives Exempt from Certification," to provide for the safe use of blue *Galdieria* extract as a color additive at levels consistent with good manufacturing practice in: (1) Beverages and beverage bases, non-alcoholic; (2) breakfast cereals; (3) chewing gum; (4) confections and frostings; (5) dairy product analogs; (6) frozen dairy desserts and mixes; (7) fruit and water ices; (8) gelatins, puddings, and fillings; (9) hard candy and cough drops; (10) milk products; (11) processed fruits and fruit juices; (12) processed vegetables and vegetable juices; and (13) soft candy.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because the substance occurs naturally in the environment, and the proposed action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that would warrant at least an environmental assessment (see 21 CFR 25.21). 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: September 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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