www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Memorandum from B. Petigara-Harp, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors (OCAC), Office of Commissioner, Office of Chief Scientist, FDA to S. DiFranco, Regulatory Management Branch (RMB), Division of Food Ingredients (DFI), Office of Premarket Additive Safety (OPMAS), HFP, FDA, April 21, 2025.
2. Memorandum from H. Thapa, Chemistry Evaluation Branch, DFI, OPMAS, HFP, FDA to S. DiFranco, RMB, DFI, OPMAS, HFP, FDA, April 21, 2025.
3. Memorandum from T. Thurmond, Toxicology Review Branch (TRB), DFI, OPMAS, HFP, FDA to S. DiFranco, RMB, DFI, OPMAS, HFP, FDA, April 21, 2025.
4. Memorandum from Y. Zang, Toxicology Review Team, DFI, Office of Food Additive Safety (OFAS), Center for Food and Human Nutrition (CFSAN), FDA, to S. DiFranco, DFI, OFAS, CFSAN, FDA, June 9, 2021.

List of Subjects in 21 CFR Part 73

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73–LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.69 is amended by revising paragraph (c) to read as follows:

§ 73.69 Butterfly pea flower extract.

* * * * *

(c) *Uses and restrictions.* Butterfly pea flower extract may be safely used for coloring alcoholic beverages, sport and energy drinks, flavored or carbonated water, fruit drinks (including smoothies and grain drinks), carbonated soft drinks (fruit-flavored or juice, ginger ale, and root beer), fruit and vegetable juice, nutritional beverages, chewing gum, teas, coated nuts, liquid coffee creamers (dairy and non-dairy), ice cream and frozen dairy desserts, hard candy, dairy and non-dairy drinks, fruit preparations in yogurts, soft candy, ready-to-eat cereals, crackers, snack mixes, hard pretzels, plain potato chips (restructured or baked), and plain corn chips, tortilla chips, and multigrain chips. Amounts must be consistent with good manufacturing practice. Butterfly pea flower extract may not be used for coloring foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

* * * * *

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08248 Filed 5–9–25; 8:45 am]

BILLING CODE 4164–01–P

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of galdieria extract blue, derived from unicellular red algae (*Galdieria sulphuraria*), in various food categories at levels consistent with good manufacturing practice (GMP). We are taking this action in response to a color additive petition (CAP) submitted by Fermentalg (Fermentalg or petitioner).

DATES: This order is effective June 26, 2025. See section XI of this document for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the order must be submitted by June 11, 2025.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of June 11, 2025. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–C–0925 for ''Listing of Color Additives Exempt from Certification; Galdieria Extract Blue.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We

will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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, 240–402–7500.

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 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:

I. Introduction

In the **Federal Register** of September 9, 2021 (86 FR 50495), FDA announced that we filed a color additive petition (CAP 1C0320) submitted by Fermentalg, 4 Rue Rivière, 33500 Libourne, France. The petition proposed that FDA 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 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). (In the filing notice for CAP 1C0320, the color additive was called ''blue galdieria extract.'' After the filing notice was published, the name was changed to ''galdieria extract blue.'')

II. Background

Galdieria extract blue is a blue liquid or powder prepared from the aqueous extraction of the dried biomass of *Galdieria sulphuraria,* a naturally occurring species of red microalgae. Galdieria extract blue contains C-phycocyanin, the principal coloring component, and may contain authorized food-grade carriers and antioxidants to standardize the color intensity and stabilize the color additive.

Production of the *G. sulphuraria* biomass is carried out by heterotrophic fermentation with no reported instances of pathogenicity or toxigenicity. The petitioner states that the production strain was deposited in the Culture Collection of Algae and Protozoa, Scottish Marine Institute, in Dunbeg, Oban, Scotland. Using a fed-batch or continuous process for providing the fermentation medium, the production strain is contained in an enclosed fermentation vessel, which avoids potential contamination by bacteria, cyanobacteria, fungi, or environmental contaminants such as heavy metals and pesticides that could otherwise be encountered in open ponds.

The finished biomass is concentrated, washed with water to remove the majority of culture medium and antifoam agent, mechanically lysed, and subjected to extraction with water, which results in a crude extract. The crude extract consists of a mixture of C-phycocyanin and other water-soluble proteins, minerals, and carbohydrates, which is then treated with a carbohydrase enzyme that digests the carbohydrates. The resulting extract is purified with consecutive filtrations and can be in a liquid form, or in a powdered form using spray-drying or other drying technologies (Ref. 1).

The petitioner proposed the following specifications for galdieria extract blue: lead, not more than 0.5 milligram/kilogram (mg/kg) (0.5 part per million (ppm)); cadmium, not more than 1 mg/kg (1 ppm); arsenic, not more than 0.5 mg/kg (0.5 ppm); mercury, not more than 0.05 mg/kg (0.05 ppm). FDA has determined that the petitioner's data support that lead, cadmium, and arsenic should all have a specification of not more than 0.5 mg/kg. The petitioner's data support a specification of not more than 0.05 mg/kg for mercury (Ref. 1).

III. Safety Evaluation

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive may not be listed for a proposed use unless the data and other information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

To determine whether a color additive is safe under the general safety clause, the FD&C Act requires FDA to conduct a fair evaluation of the available data and consider, among other relevant factors: (1) probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, devices, or cosmetics because of the use of the additive; (2) cumulative effect, if any, of such additive in the diet of man or animals, taking into account chemically or pharmacologically related substance or substances in such diet; and (3) safety factors recognized by experts as appropriate for the use of animal experimentation data (see section 721(b)(5)(A)(i) through (iii) of the FD&C Act).

As part of our safety evaluation to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability, the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us.

IV. Safety of the Petitioned Use of the Color Additive

A. Dietary Exposure Estimate

The petitioner provided information on the proposed food categories and the corresponding maximum use levels of galdieria extract blue as a color additive that represent levels consistent with GMP for each proposed food category (Ref. 2). The petitioner used food consumption data from the 2017–2018 National Health and Nutrition Examination Survey (NHANES) to

estimate the dietary exposure to galdieria extract blue from the petitioned uses. The petitioner estimated the eaters-only (*i.e.,* only those individuals in the population that consume the foods of interest) dietary exposure to galdieria extract blue to be 273 mg/person/day (mg/p/d) at the mean and 630 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older; and 261 mg/p/d at the mean and 575 mg/p/d at the 90th percentile for children aged 2–5 years (Ref. 2).

The petitioner indicated that the typical level of C-phycocyanin in galdieria extract blue is 34 percent. FDA estimated the dietary exposure to C-phycocyanin by multiplying the dietary exposure to galdieria extract blue by the typical C-phycocyanin level of 34 percent, resulting in an estimated eaters-only dietary exposure to the principal coloring component from the petitioned uses to be 93 mg/p/d at the mean and 214 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older; and 89 mg/p/d at the mean and 196 mg/p/d at the 90th percentile for children aged 2–5 years (Ref. 2).

The petitioner stated that galdieria extract blue will likely be used in the petitioned food categories as a substitute for spirulina extract, a related C-phycocyanin-based color additive derived from *Arthrospira platensis.* Given that galdieria extract blue will likely be used in the petitioned food categories as a substitute for spirulina extract, and given the structural similarity of the phycocyanobilin chromophores in these two sources, we would not expect an increase in the current upper-bound cumulative estimated daily intake (CEDI) for C-phycocyanin of 1140 mg/p/d in the U.S. diet from the petitioned uses of galdieria extract blue. Therefore, the current upper-bound CEDI of C-phycocyanin encompasses the petitioned uses of galdieria extract blue (Ref. 2).

B. Toxicological Considerations

To support the safety of the petitioned use of galdieria extract blue, the petitioner provided peer-reviewed studies, data derived from publicly available databases, and referenced previously submitted color additive petitions. The data and information provided included: (1) the results of a subchronic (90-day rat) toxicology study on the *G. sulphuraria* C-phycocyanin extract and the *G. sulphuraria* biomass, (2) two genotoxicity assays (bacterial reverse mutation test and *in vitro* micronucleus test), (3) a safety narrative that discusses the results of their safety assessment of the color additive, (4) a narrative that discusses the current published literature that supports the safe use of the color additive, and (5) a discussion on FDA's previous reviews of color additive petitions regarding the safety of C-phycocyanin (78 FR 49117, August 13, 2013; 79 FR 20095, April 11, 2014; 82 FR 30731, July 3, 2017). The petitioner also addressed the potential for allergenicity associated with the color additive (Ref. 3).

The petitioner included data from a 90-day subchronic study that used multiple doses of galdieria extract blue. The study also included a post-treatment recovery period of 28 days to facilitate evaluation of the persistence, reversibility, or delayed occurrence of toxic effects. C-phycocyanin extract derived from *Spirulina platensis* (reclassified as *A. platensis*) was used as a reference test item, for a period of 90 days with the same dosing procedure as for galdieria extract blue. The petitioner reported no instances of mortality among the animals treated with galdieria extract blue or C-phycocyanin extract derived from *A. platensis* throughout the study. All control animals and treated animals survived during the treatment period of 90 days and during the 28-day recovery period. No gross treatment-related changes were observed at necropsy. FDA identified no major deficiencies that would invalidate the study results for its intended purpose, and no results from this study suggest that galdieria extract blue produces adverse effects for any of the parameters evaluated during the study. The petitioner concluded that under the test conditions, the no observed adverse effect level (NOAEL) for galdieria extract blue was the highest dose tested, 4000 mg/kg body weight (bw)/d (Ref. 3).

The petitioner also included data from a 90-day subchronic study that used multiple doses of the *G. sulphuraria* biomass. Following completion of the study, the petitioner stated that the *G. sulphuraria* biomass was well-tolerated at all dose levels with no mortality or toxicity observed. The petitioner concluded that under the test conditions, the NOAEL for the *G. sulphuraria* biomass was the highest dose tested, 5000 mg/kg bw/d (Ref. 3).

An Ames test (bacterial reverse mutation test) and an *in vitro* micronucleus test were also conducted on both galdieria extract blue and the *G. sulphuraria* biomass. Following completion of the studies, the petitioner concluded that the test items did not show any mutagenic activity in the Ames test, and that the *in vitro* micronucleus test demonstrated no statistically significant increase in micronucleated cells. Based on the data submitted by the petitioner, FDA agrees with the petitioner's findings that galdieria extract blue was not a mutagen in the Ames test under the conditions of the assay, nor did it induce chromosomal damage under the conditions of the micronucleus test.

The petitioner's discussion of the potential allergenicity of C-phycocyanin included a pepsin gastric simulation assay, a bioinformatics analysis of potential proteins encoded in the genome DNA of *G. sulphuraria* that could be associated with allergenicity, and the results of petitioner's literature search. The results of the pepsin gastric simulation assay indicated that C-phycocyanin derived from *G. sulphuraria* is likely to undergo rapid degradation under normal digestive conditions, suggesting that it may be non-allergenic. The results of the bioinformatic analysis only identified sequences from highly conserved gene families, and these sequences demonstrated lower similarity to *G. sulphuraria* proteins than to members of the same gene family in common foodstuffs. Therefore, the color additive is proposed to have low allergenic risk. The petitioner's literature search identified one case report of an atopic person having an anaphylactic reaction to C-phycocyanin derived from *A. platensis.* The petitioner considered the response to be idiosyncratic; no other reports of a similar reaction to C-phycocyanin were identified. Given the results of the pepsin gastric simulation assay, the bioinformatic analysis, and the search of the literature, we concur with the petitioner's conclusion that galdieria extract blue is unlikely to produce an allergic reaction and find no additional data suggesting galdieria extract blue is associated with allergic or hypersensitivity reactions (Ref. 3).

The petitioner's safety narrative included a structural comparison of C-phycocyanin from *G. sulphuraria* and C-phycocyanin from *A. platensis,* noting that C-phycocyanins from *G. sulphuraria* and *A. platensis* belong to the same C-phycocyanin family and stated that their primary sequences of the protein backbone are highly similar, with no significant differences between their 3-dimensional organizations. The petitioner stated that, despite amino acid differences between the two C-phycocyanins, the differences did not seem to affect any of the molecular recognition properties of the C-phycocyanins, neither in their structural organization nor in the chromophore binding, and therefore, the functional properties are likely to be similar (Ref. 3).

Based on our review of the safety data provided by the petitioner, and our independent review of the current published literature, which do not present evidence of safety concerns for galdieria extract blue at the expected dietary exposures, and given that the estimated 90th percentile dietary exposure for the color additive for the U.S. population aged 2 years and older (630 mg/p/d) does not exceed the NOAEL of 4000 mg/kg bw/d, we conclude that galdieria extract blue is safe for the petitioned uses.

VI. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of galdieria extract blue as a color additive 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) is safe, provided the amount of galdieria extract blue does not exceed levels consistent with GMP.

We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of this color additive as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of galdieria extract blue is not necessary to protect the public health.

This final order is expected to result in expanded production options and is considered an E.O. 14192 deregulatory action.

VII. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impact

As we stated in the September 9, 2021, **Federal Register** notification of petition for CAP 1C0320 (86 FR 50495 at 50495 to 50496), the petitioner claimed that this action is categorically excluded under § 25.32(r) (21 CFR 25.32(r)) because the substance occurs naturally in the environment, and the proposed action does not significantly alter the concentration or distribution of the substance, its metabolites, or degradation products in the environment, and that, to their knowledge, no extraordinary circumstances exist that would warrant at least an environmental assessment (see § 25.21 (21 CFR 25.21)). We did not receive any new information or comments regarding this claim of categorical exclusion. We considered the petitioner's claim of categorical exclusion and determined that this action is categorically excluded under § 25.32(r). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act (21 U.S.C. 379e). This order is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this order should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final orders that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

XI. Objections

This order is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Memorandum from N. Belai, Color Technology Branch, Division of Color Certification and Technology, Office of Cosmetics and Colors, Office of the Chief Scientist, FDA to S. Hice, Innovative Foods Staff (IFS), Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI), Human Foods Program (HFP), FDA, April 28, 2025.

2. Memorandum from H. Lee, Chemistry Evaluation Branch, DFI, Office of Pre-Market Additive Safety (OPMAS), OFCSDSI, HFP, FDA to S. Hice, IFS, OFCSDSI, HFP, FDA, April 28, 2025.
3. Memorandum from S. Thurmond, Toxicology Review Branch, DFI, OPMAS, OFCSDSI, HFP, FDA to S. Hice, IFS, OFCSDSI, HFP, FDA, April 28, 2025.

List of Subjects in 21 CFR Part 73

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Add § 73.167 to subpart A to read as follows:

§ 73.167 Galdieria extract blue.

(a) *Identity.* (1) The color additive galdieria extract blue is a liquid or powder prepared by the filtered aqueous extraction of the dried biomass of a non-pathogenic and non-toxigenic strain of *Galdieria sulphuraria.* The biomass is prepared by heterotrophic fermentation of *G. sulphuraria.* The color additive contains C-phycocyanin as the principal coloring component.

(2) Color additive mixtures for food use made with galdieria extract blue may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Galdieria extract blue must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 0.5 milligram/kilogram (mg/kg) (0.5 parts per million (ppm)).

(2) Arsenic, not more than 0.5 mg/kg (0.5 ppm).

(3) Mercury, not more than 0.05 mg/kg (0.05 ppm).

(4) Cadmium, not more than 0.5 mg/kg (0.5 ppm).

(c) *Uses and restrictions.* Galdieria extract blue may be safely used for coloring 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), at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08250 Filed 5–9–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0321]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Cocoa Beach, FL

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Atlantic Ocean near Cocoa Beach, Florida. This safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the Thunder on Cocoa Beach powerboat racing event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Jacksonville or a designated representative.

DATES: This rule is effective daily from 8 a.m. until 6:30 p.m. on May 16, 2025, through May 18, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0321 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Marine Safety Technician First Class Alex Christensen, Marine Safety Unit Port Canaveral, U.S. Coast Guard; telephone 321–868–5921, email *alex.m.christensen@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard lacks sufficient time to provide for a comment period and then consider those comments before issuing the rule since this rule is needed by May 16, 2025. We must establish the safety zone by May 16, 2025, to ensure the safety of the public, and vessels transiting the waters of the Atlantic Ocean near Cocoa Beach, Florida during the race event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because prompt action is needed to respond to the potential dangers to the public and vessels during the race.