

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-phycoerythrin 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.*

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**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](mailto: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.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port (COTP) Jacksonville has determined that potential hazards associated with Thunder on Cocoa Beach powerboat races will be a safety concern for anyone within the described boundary of this safety zone. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the event is taking place.

### IV. Discussion of the Rule

This rule establishes a safety zone daily from 8 a.m. until 6:30 p.m. on May 16, 2025, through May 18, 2025. The safety zone will cover all navigable waters within a set boundary located in the Atlantic Ocean off the coast of Cocoa Beach, FL. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during this event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP Jacksonville or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the Coast Guard assigned to units under the operational control of the Coast Guard Sector Jacksonville. Requests for entry will be considered and reviewed on a case-by-case basis.

Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated area by contacting the Captain of the Port Jacksonville or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Jacksonville or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Jacksonville or a designated representative. The Coast Guard will provide notice of the safety zone by Broadcast Notice to Mariners via VHF-FM marine channel 16, and/or by on-scene designated representatives.

### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

#### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on: (1) This rule involves a safety zone that will prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within a limited area on the navigable waters of Cocoa Beach, Florida, during a racing event lasting ten and a half hours daily for three days; (2) Although persons and vessels may not enter, transit through, anchor in, or remain within the zone without authorization from the COTP or a designated representative, they will be able to safely transit around this safety zone; (3) persons and vessels may still enter, transit through, anchor in, or remain within the areas during the enforcement period if authorized by the COTP or a designated representative; and (4) the Coast Guard will provide advance notification of the zone to the local maritime community by Broadcast Notice to Mariners, or by on-scene designated representatives.

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

#### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

#### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

#### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

## F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only ten and a half hours each day over a three-day period that will prohibit entry within a described boundary off the coast of Cocoa Beach, FL. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T07–0321 to read as follows:

### § 165.T07–0321 Safety Zone; Atlantic Ocean, Cocoa Beach, FL.

(a) *Location.* The following area is a safety zone: All waters of the Atlantic Ocean, from surface to bottom, encompassed by a line connecting the following points beginning at 28°18.688' N, 80°36.345' W, thence to 28°18.685' N, 80°35.617' W, thence to 28°22.143' N, 80° 35.225' W, thence to 28°22.330' N, 80°35.996' W, thence back to the beginning point. These coordinates are based on the 1984 World Geodetic System (WGS 84).

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol

Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Jacksonville in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP Jacksonville or designated representative.

(2) Designated representatives may control vessel traffic throughout the enforcement area as determined by the prevailing conditions.

(3) To seek authorization to enter, contact the COTP or the COTP's representative by telephone at (904) 714–7557, or an on-scene designated representative via VHF–FM radio on channel 16. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Jacksonville or a designated representative.

(d) *Enforcement period.* The safety zone will be enforced daily, from 8 a.m. to 6:30 p.m., from May 16, 2025, through May 18, 2025. The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners on VHF–FM marine channel 16.

J.D. Espino-Young,

*Captain, U.S. Coast Guard, Captain of the Port Sector Jacksonville.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 217

[Docket No. 250505–0077]

RIN 0648–BN12

### Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Lower Columbia River Dredged Material Management Plan, Oregon and Washington

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS, upon request from the U.S. Army Corps of Engineers (USACE), issues regulations to govern the

unintentional taking of marine mammals incidental to implementation of the Lower Columbia River Dredged Material Management Plan in Oregon and Washington over 5 years (2027–2032). These regulations, which allow for the issuance of a Letter of Authorization (LOA) for the incidental take of marine mammals during the specified activities and timeframes, prescribe the permissible methods of taking and effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as monitoring and reporting requirements.

**DATES:** This rule is effective from November 1, 2027 through February 29, 2032.

**ADDRESSES:** A copy of the USACE's application and any supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-army-corps-engineers-lower-columbia-river-dredged-material>.

In case of problems accessing these documents, please call the contact listed below.

**FOR FURTHER INFORMATION CONTACT:** Robert Pauline, Office of Protected Resources, NMFS, (301) 427–8401.

#### SUPPLEMENTARY INFORMATION:

#### Purpose and Need for Regulatory Action

This rule establishes a framework under the authority of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the USACE's construction activities related to the Lower Columbia River (LCR) Dredged Materials Management Plan (DMMP).

We received an application from the USACE requesting 5-year regulations and authorization to take multiple species of marine mammals. Take is anticipated to occur incidental to impact and vibratory pile driving, by Level A and Level B harassment only. Please see Background below for definitions of harassment.

#### Legal Authority for the Action

Section 101(a)(5)(A)(i) of the MMPA (16 U.S.C. 1371(a)(5)(A)(i)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to 5 years if, after notice and public comment, the