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

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**).

1. Memorandum from N. Belai, Color Technology Team, OCAC, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, March 19, 2015.
2. Memorandum from H. Lee, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, January 30, 2015.
3. Letter from D. Keefe, Office of Food Additive Safety, CFSAN, FDA to H. Newman, Desert Lake Technologies, LLC, Agency Response Letter GRAS Notice 000424, December 6, 2012, (*http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm335743.htm*).
4. Memorandum from T. Walker, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, April 2, 2015.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR 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 73.530 is amended by revising paragraph (c) to read as follows:

§ 73.530 Spirulina extract.

* * * * *

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), and coating formulations applied to dietary supplement tablets and capsules, 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.

* * * * *

■ 3. Section 73.1530 is added to subpart B to read as follows:

§ 73.1530 Spirulina extract.

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis.* The color additive contains phycocyanins as the principal coloring components.

(2) Color additive mixtures for drug use made with spirulina extract may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Spirulina extract 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 2 milligrams per kilogram (mg/kg) (2 parts per million (ppm));

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

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring coating formulations applied to drug tablets and capsules, at levels consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall 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: August 14, 2015.

Susan Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–20676 Filed 8–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2015–0216]

RIN 1625–AA08

Special Local Regulation; Suncoast Super Boat Grand Prix; Gulf of Mexico, Sarasota, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending a special local regulation for the Suncoast Super Boat Grand Prix that occurs on the waters of the Gulf of Mexico near Sarasota, Florida. The event is scheduled to take place annually on the first Friday, Saturday, and Sunday of July from 10 a.m. to 5 p.m. The amendment is needed in order to protect the safety of race participants, participant vessels, spectators, and the general public on the navigable waters of the United States. The amended special local regulation will restrict vessel traffic on the waters near the event by establishing the following three areas: A race area, where all persons and vessels, except those persons and vessels participating in the high speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within; a spectator area, where all vessels must be anchored or operate at No Wake Speed; and an enforcement area where designated representatives may control vessel traffic as determined by prevailing conditions.

DATES: This rule is effective September 21, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2015–0216. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the

Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade Brett S. Sillman, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228–2191, email *D07-SMB-Tampa-WWM@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is proposing to amend the Special Local Regulation on the waters of the Gulf of Mexico in the vicinity of Sarasota, Florida during the Suncoast Super Boat Grand Prix. The event is scheduled to take place the first Friday, Saturday, and Sunday in July from 10 a.m. to 5 p.m. This final rule is necessary to protect the safety of race participants, participant vessels, spectators, and the general public on the navigable waters of the United States during the event.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard's authority to establish special local regulations: 33 U.S.C. 1233.

The purpose of the proposed rule is to provide for the safety of life on navigable waters of the United States during the Suncoast Super Boat Grand Prix.

C. Comments, Changes, and the Final Rule

There were no comments related to this event during the comment period and there was no request for a public meeting made during the comment period.

This special local regulation will be enforced annually during the first Friday, Saturday, and Sunday of July from 10 a.m. to 5 p.m. The special local regulations will establish the following three areas: (1) A race area, where all persons and vessels, except those persons and vessels participating in the high speed boat races, are prohibited from entering, transiting through, anchoring in, or remaining within; (2) a spectator area, where all vessels must be anchored or operate at No Wake Speed; and (3) an enforcement area where designated representatives may control vessel traffic as determined by the prevailing conditions.

Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area or enforcement area by contacting the Captain of the Port St. Petersburg by telephone at (727) 824–7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area or enforcement area is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative.

D. 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 or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The economic impact of this final rule is not significant for the following reasons: (1) The special local regulations will be enforced for only seven hours a day for three days; (2) although persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the race area or enforcement area without authorization from the Captain of the Port St. Petersburg or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the race area and enforcement area if authorized by the Captain of the Port St. Petersburg or a designated representative; and (4) the Coast Guard would provide advance notification of the special local regulations to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners and/or on-scene designate representatives.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

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 proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

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

5. Federalism

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 proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. 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 proposed rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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.

12. Energy Effects

This rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Revise § 100.720 to read as follows:

§ 100.720 Special Local Regulations; Suncoast Super Boat Grand Prix, Gulf of Mexico; Sarasota, FL.

(a) *Regulated areas.* The following regulated areas are established as special local regulations. All coordinates are North American Datum 1983.

(1) *Race area.* All waters of the Gulf of Mexico contained within the following points: 27°18.19′ N., 82°34.29′ W., thence to position 27°17.42′ N., 82°35.00′ W., thence to position 27°18.61′ N., 82°36.59′ W., thence to position 27°19.58′ N., 82°35.54′ W., thence back to the original position 27°18.19′ N., 82°34.29′ W.

(2) *Spectator area.* All waters of Gulf of Mexico no less than 500 yards from the race area and/or as agreed upon by the Coast Guard and race officials.

(3) *Enforcement area.* All waters of the Gulf of Mexico encompassed within the following points: 27°17.87′ N., 82°33.93′ W., thence to position 27°16.61′ N., 82°34.69′ W., thence to position 27°18.53′ N., 82°37.52′ W., thence to position 27°20.04′ N., 82°35.76′ W., thence back to the original position 27°17.87′ N., 82°33.93′ W.

(b) *Definition.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port St. Petersburg in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the race area unless an authorized race participant.

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

(3) All vessels are to be anchored and/or operate at a No Wake Speed in the spectator area. On-scene designated representatives will direct spectator vessels to the spectator area.

(4) All vessel traffic not involved with the event shall enter and exit Sarasota Bay via Big Sarasota Pass and stay well clear of the enforcement area.

(5) New Pass will be closed to all inbound and outbound vessel traffic at the COLREGS Demarcation Line. Vessels are allowed to utilize New Pass to access all areas inland of the Demarcation Line via Sarasota Bay. New Pass may be opened at the discretion of the Captain of the Port.

(6) Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the regulated areas by contacting the Captain of the Port St. Petersburg by telephone at (727) 824–7506, or a designated representative via VHF radio on channel 16. If authorization is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative.

(d) *Enforcement date.* This section will be enforced annually the first Friday, Saturday, and Sunday of July from 10 a.m. to 5 p.m. EDT daily.

Dated: June 15, 2015.

G.D. Case,

Captain, U.S. Coast Guard, Captain of the Port St. Petersburg.

[FR Doc. 2015–20741 Filed 8–20–15; 8:45 am]

BILLING CODE 9110–04–P