Energy for Peace (Bangkok, Thailand). (023535000; 4868000)), ISBN 974–7399–29–6, 1985.

51. Jimes, S., ''Clostridium Botulinum Type E in Gulf Coast Shrimp and Shucked Oysters and Toxin Products as Affected by Irradiation Dosage, Temperature, Storage Time, and Mixed Spore Concentrations,'' dissertation submitted to Louisiana State University, pp. ix and 1, 1967.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and record keeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

■ 1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 2. Section 179.26 is amended in the table in paragraph (b) by adding item 14 to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(b) * * *

Use	Limitations
* * *	* *
14. For control of food-borne pathogens in, and extension of the shelf-life of, chilled or frozen raw, cooked, or partially cooked crustaceans or dried crustaceans (water activity less than 0.85), with or without spices, minerals, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA.	Not to exceed 6.0 kGy.

* * * * *

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07926 Filed 4–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2013–N–0568]

Physical Medicine Devices; Reclassification of Stair-Climbing Wheelchairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify stair-climbing wheelchairs, a class III device, into class II (special controls) based on new information and subject to premarket notification, and further clarify the identification.

DATES: This order is effective April 14, 2014.

FOR FURTHER INFORMATION CONTACT: Mike Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at

181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify this device in the **Federal Register** of June 12, 2013 (78 FR 35173). FDA received and has considered 285 comments on this proposed order, as discussed in section II. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to stair-climbing wheelchairs and, therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As further described in section III, a meeting of a device classification panel described in section 513(b) of the FD&C Act took place on December 12, 2013 (78 FR 66942, November 7, 2013), to discuss whether stair-climbing wheelchairs should be reclassified or remain in class III, and the panel recommended that the device be reclassified into class II because there was sufficient information to establish special controls. FDA is not aware of new information since the panel that would provide a basis for a different recommendation or findings.

II. Public Comments in Response to the Proposed Order

In response to the June 12, 2013 (78 FR 35173), proposed order to reclassify stair-climbing wheelchairs, FDA received 285 comments. Comments were received from consumers and other stakeholders who are personally or professionally associated with a stair-climbing wheelchair user. These individuals included users, family members, friends, and professionals such as occupational and physical therapists. Several veterans and patient advocacy groups also responded. The majority of the comments received advocated that this device be classified into class II, but the comments did not include information relevant to the safety, effectiveness, or risks of these devices, aside from personal experience, which focused on payment and availability issues and are not directly relevant to the types of information necessary for a classification decision. One comment from a representative of a patient advocacy coalition opposed the reclassification to class II, stating that, ''This change in classification would result in greater risk for some of our nation's most vulnerable consumers,'' and citing safety data published on FDA's Web site and described in section 5 of the FDA's Executive Panel Summary (Ref. 1), as well as the risks of the device as outlined in section V of the proposed order.

The Agency disagrees with this comment regarding risks and believes it has identified the relevant risks to health (see section V of the proposed order and sections III and IV of this document) and special controls that will be effective in mitigating these risks (see section VIII of the proposed order and the codified language of this document). These risks and mitigations were based on the input of the original classification panel in 1976; data in PMAs available to FDA under section 520(h)(4) of the FD&C Act, added by FDAMA; the information in the 2012 reclassification petition (Ref. 2); the information gathered from FDA's Manufacturer and User Facility Device Experience (MAUDE) database and FDA's literature review (see FDA's Executive Panel Summary, Ref. 1); and the recommendations of the December 12, 2013, Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee (Ref. 3), as further described in section III of this document. Further, FDA believes that the identified special controls mitigate these risks and provide a reasonable assurance of safety and effectiveness in this patient population.

III. Deliberations of the Panel

On December 12, 2013, the Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee (the Panel) considered the reclassification of stair-climbing wheelchair devices from class III to class II (special controls) (Ref. 3). The Panel was asked to provide input on the risks to health, safety, and effectiveness of these devices.

The reclassification of stair-climbing wheelchair devices was supported by the Panel. At the Panel, FDA proposed a new identification for stair-climbing wheelchairs that differed from the identification given in the proposed order. This change was proposed to remove the language for endless belt tracks, and the Panel supported this revision. The new identification is to encompass the other modes of propulsion that may be used and have been approved for other stair-climbing wheelchairs. The new proposed device identification supported by the Panel is, ''A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.''

The panelists agreed with the FDA's list of risks to health from the June 2013 proposed order related to stair-climbing wheelchairs and added suggestions related to pressure sores, bruising, use error, and falls and associated injuries. The Panel expressed concern that the method of sustaining injury for pressure sores and bruising is dramatically different as discussed in this document and recommended that bruising and pressure sores be presented as two separate risks. The Panel also requested an expansion to the description of the use error risk to include users injuring themselves by shifting their position or posture while in the device. Additionally, the Panel asked that subdural hematoma be specifically identified as a clinical risk to health, as a result of the fall. After the Panel, FDA further reviewed the available evidence and noted that skin rash had been identified in the reported adverse events and presented to the Panel. Therefore, FDA has amended the list of risks to include adverse tissue reactions (e.g., rash, irritation). FDA believes this will

be addressed by the existing special control (biocompatibility).

Based upon the Panel's input and FDA's review, FDA has updated the risks to the following:

- Instability: Instability of the device could result in the device tipping over, slipping off an edge (e.g., curb or stair), or sliding down stairs, or use in certain environmental conditions that minimizes frictional coefficient, may result in injury to the user.
- Entrapment: The device may entrap a user or a body part if it moves unintentionally, shifts the user into a position from which they are unable to extricate themselves, or pinches a body part against a solid object.
- Use error: A stair-climbing wheelchair may be misused if the user is not properly secured within the seat or if the device is used outside of certain environmental conditions or prescribed step dimensions, structural characteristics. The user could also be positioned in the seat in such a way as to cause injury.
- Falls and associated injuries: If the user falls out of the chair or the device falls or rolls over a body part of the user or another individual (e.g., caregiver), it can result in serious injury, including fracture, subdural hematoma, or other injuries.
- Battery/electrical/mechanical failure: The device may fail and place the user in an unsafe position (e.g., middle of a street intersection, on stairs). This may result from failure of device critical device components (electronics, battery, brakes) or the device changing operational modes unexpectedly.
- Pressure sores: Individuals restricted to a wheelchair are at increased risk of pressure sores. Pressure sores develop due to pressure, shear force, friction and a combination of all these factors. Pressure sores may develop due to poor wheelchair position or inadequate pressure relief regimen. Pressure points can cause cell death and a resulting pressure sore. Pressure points are typically found at bony prominences, areas that are squeezed due to a poor fitting wheelchair, or areas with increased pressure such as the sacrum when a person has poor position in the wheelchair.
- Bruising: Bruising may result from the user experiencing jarring forces when transitioning over different surfaces or from colliding with solid objects.
- Burns: As a result of battery overheating, electrical failure, or ignition of flammable materials, the user may sustain burns.
- Electric shock: The user may experience electric shock as a result of battery or electrical failure.
- Electromagnetic interference: The device may interfere with the operation of other electrical devices or be susceptible to interference from other electrical devices.
- Adverse tissue reaction: The patient-contacting materials of the device may produce local adverse effects, such as skin rash or irritation.

The Panel found that stair-climbing wheelchairs are not life supporting or life sustaining. The Panel also agreed that FDA's list of special controls from the June 2013 proposed order would mitigate the risks and provide reasonable assurance of safety and effectiveness for stair-climbing wheelchair devices. Panelists expressed concerns regarding the specificity of the proposed special controls given the potential variations in device designs, environmental conditions, and user abilities. The Panel commented that the special controls for endurance testing are duplicative of the tests outlined in fatigue testing. Panelists agreed that general controls, required for all medical devices, are insufficient to provide a reasonable assurance of safety and effectiveness for stair-climbing wheelchair devices.

FDA agrees with the special control recommendations and has revised the special controls accordingly (see section IV., The Final Order). Table 1 shows how FDA believes that the risks to health identified and listed in this document can be mitigated by the special controls.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR STAIR-CLIMBING WHEELCHAIR

Identified risk	Mitigation measures
Instability	Performance Testing. Usability Testing. Software Verification and Validation. Design Characteristics. Labeling.
Entrapment	Performance Testing. Usability Testing. Software Verification and Validation. Labeling.
Use Error	Usability Testing. Labeling.
Falls and Associated Injuries	Performance Testing. Usability Testing. Labeling.
Battery/Electrical/Mechanical Failure	Performance Testing. Electrical Safety Testing. Software Verification and Validation. Battery Testing. Labeling.
Pressure Sores	Design Characteristics. Usability Testing. Labeling.
Bruising	Design Characteristics. Usability Testing. Labeling.
Burns	Battery Testing. Flammability Testing. Electrical Safety Testing. Labeling.
Electrical shock	Battery Testing.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR STAIR-CLIMBING WHEELCHAIR—Continued

Identified risk	Mitigation measures
Electromagnetic Interference	Electrical Safety Testing. Labeling. Electromagnetic Compatibility Testing.
Adverse Tissue Reaction	Labeling. Biocompatibility Testing.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings, in part, as published in the preamble to the proposed order. FDA has made revisions in this final order in response to the comments received (see section II) and the deliberations of the Panel (see section III). As published in the proposed order, FDA is issuing this final order to reclassify stair-climbing wheelchairs from class III to class II and establish special controls by revising § 890.3890 (21 CFR 890.3890). The identification for § 890.3890(a) has been revised to provide a more accurate description of devices in this classification.

In response to the input of the Panel, FDA also made refinements to the proposed special controls. FDA modified the special controls requirements for stair-climbing wheelchair devices including: Endurance testing was removed since it is duplicative of fatigue testing.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of stair-climbing wheelchair devices, and therefore, this device type is not exempt from premarket notification requirements.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, FDA is revoking the requirements in § 890.3890 related to the classification of stair-climbing wheelchairs as class III devices and codifying the reclassification of stair-climbing wheelchairs into class II.

VIII. 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 all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Executive Summary prepared for the December 12, 2013, meeting of the Orthopedic and Rehabilitation Panel (available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM378085.pdf*).
2. Petition from Deka Research & Development Corp., October 22, 2012 (Docket No. FDA–2012–P–1155) (available at: *http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-1155-0001*).
3. Transcript of the December 12, 2013, meeting of the Orthopedic and Rehabilitation Panel (available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM381590.pdf*).

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 890.3890 is revised to read as follows:

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

(i) Fatigue testing;

(ii) Resistance to dynamic loads (impact testing);

(iii) Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

(iv) Demonstration of adequate stability of the device on inclined planes (forward, backward, and lateral);

(v) Demonstration of the ability of the device to safely ascend and descend obstacles (i.e., stairs, curb); and

(vi) Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

(3) The skin-contacting components of the device must be demonstrated to be biocompatible.

(4) Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

(5) Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(6) Performance testing must demonstrate battery safety and evaluate longevity.

(7) Performance testing must evaluate the flammability of device components.

(8) Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device and the principles of how the device works;

(ii) A clear description of the appropriate use environments/conditions, including prohibited environments;

(iii) Preventive maintenance recommendations;

(iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

(v) A detailed summary of the device-related adverse events and how to report any complications.

(9) Clinician labeling must include all the information in the Patient labeling noted in paragraph (b)(8) of this section but must also include the following:

(i) Identification of patients who can effectively operate the device; and

(ii) Instructions on how to fit, modify, or calibrate the device.

(10) Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Dated: April 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08257 Filed 4–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2014–0189]

Special Local Regulations; Recurring Marine Events in the Seventh Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Conch Republic Navy Parade and Battle Special Local Regulation in the Gulf of Mexico, from 7:00 p.m. until 8:00 p.m. on April 25, 2014. This action is necessary to ensure the safety of event participants, participant vessels, spectators, and the general public from the hazards associated with this event. During the enforcement period, no person or vessel may enter the regulated area without permission from the Captain of the Port.

DATES: The regulations in 33 CFR 100.701 Table 1 will be enforced from 7:00 p.m. until 8:00 p.m. on April 25, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Marine Science Technician First Class Ian G. Bowes, Sector Key West Prevention Department, U.S. Coast Guard; telephone 305–292–8823, email *Ian.G.Bowes@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Conch Republic Navy Parade and Battle Special Local Regulation in the Gulf of Mexico in 33 CFR 100.701 on April 25, 2014. These regulations can be found in the 2013 issue of the **Federal Register** 33 CFR 100.701.

On April 25, 2014, Conch Republic Navy LLC. is hosting the Conch Republic Navy Parade and Battle, a boat parade and simulated naval battle event that will take place approximately 150 yards offshore from Ocean Key Sunset Pier, Mallory Square and the Hilton Pier within the Key West Harbor. The event will be held on the waters of the Gulf of Mexico in Key West. Approximately 10 vessels will participate in the event.

The special local regulations encompass certain waters of the Gulf of Mexico located offshore from the island of Key West. The special local regulations will be enforced from 7:00 p.m. until 8:00 p.m. on April 25, 2014. The special local regulations area will consist of the following area: An event area, where all persons and vessels, except those persons and vessels participating in the swim event, are prohibited from entering, transiting, anchoring, or remaining. The race area is defined as all waters of the Gulf of Mexico encompassed within the following points: Starting at Point 1 in position 24°33′41″ N, 81°48′25″ W; thence to Point 2 in position 24°33′43″ N, 81°48′34″ W; thence to Point 3 in position 24°33′32″ N, 81°48′38″ W; thence to Point 4 in position 24°33′30″ N, 81°48′30″ W. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area by contacting the Captain of the Port Key West by telephone at 305–292–8727, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area is granted by the Captain of the Port Key West, or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Key West or the designated representative. The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.701 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via a Broadcast Notice to Mariners.

Dated: March 31, 2014.

A.S. Young, Sr.,

Captain, U.S. Coast Guard, Captain of the Port Key West.

[FR Doc. 2014–08368 Filed 4–11–14; 8:45 am]

BILLING CODE 9110–04–P