

number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ 2. Add § 876.5510 to subpart F to read as follows:

§ 876.5510 Temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia.

(a) *Identification.* A temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia (BPH) is a prescription use device that is inserted transurethally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men.

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

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate improvement in urinary outflow symptoms and document the adverse event profile.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following

performance characteristics must be tested:

- (i) Deployment and removal; and
- (ii) Mechanical strength.

(6) Labeling must include:

(i) Instructions for use, including the recommended training for safe use of the device;

(ii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events; and

(iii) A shelf life.

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0441]

Special Local Regulations; Marine Events Within the Fifth Coast Guard District; Washington, DC Dragon Boat Festival

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for a recurring marine event in the Fifth Coast Guard District. This regulation applies to the Washington, DC Dragon Boat Festival. This action is intended to restrict vessel traffic in a portion of the Upper Potomac River near Washington, DC, in order to provide for the safety of life on navigable waters during the event.

DATES: On May 31, 2025, from 7:30 a.m. until 6:30 p.m., the regulations in 33 CFR 100.501 will be enforced for the location identified in table 2 to 33 CFR 100.501(i)(2) for the event denominated as “Washington, DC Dragon Boat Festival.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email MDNCRMarineEvents@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.501 for the Washington, DC Dragon Boat Festival

regulated area from 7:30 a.m. to 6:30 p.m. on May 31, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. As stated in footnote one to table 2 to paragraph (i)(2), the enforcement dates and times for each of the listed events in the table are subject to change. Due to inclement weather, the Washington, DC Dragon Boat Festival has been rescheduled (for this year only) from the third weekend in May to May 31, 2025, for a one-day event. Our regulation for marine events within the Fifth Coast Guard District, § 100.501, specifies the location of the regulated area for the Washington, DC Dragon Boat Festival, which encompasses portions of the navigable waters of the Upper Potomac River. During the enforcement periods, as reflected in § 100.100(c), the operator of a vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcast.

Dated: May 21, 2025.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0385]

RIN 1625–AA00

Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of Lake Erie offshore Edgewater Beach in Cleveland, Ohio. This action is necessary to provide for the safety of life on these navigable waters during the US Rowing Beach Sprints Mini Camp. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port,