

classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, computerized behavioral therapy devices for the treatment of fibromyalgia symptoms are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for computerized behavioral therapy devices for the treatment of fibromyalgia symptoms. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

### III. Analysis of Environmental Impact

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

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control 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 management 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 882

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 882 is amended as follows:

### PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for part 882 continues to read as follows:

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

- 2. Add § 882.5804 to subpart F to read as follows:

#### § 882.5804 Computerized behavioral therapy device for the treatment of fibromyalgia symptoms.

(a) *Identification.* A computerized behavioral therapy device for the treatment of fibromyalgia symptoms is a prescription device intended to provide a computerized version of behavioral therapy for the treatment of fibromyalgia symptoms.

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

(1) Clinical data must demonstrate that the device performs as intended under the anticipated conditions of use and include the following:

- (i) Evaluation of improvement in the symptoms of fibromyalgia; and
- (ii) Evaluation of relevant adverse events.

(2) Software verification, validation, and hazard analysis must demonstrate that the device performs as intended.

(3) Physician and patient labeling must include the following:

(i) Recommended treatment regimes, including frequency and duration of use; and

(ii) A summary of the clinical data for the device, including a discussion of adverse events.

**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 No. USCG–2026–0479]

### Southern California Annual Firework Events for the Los Angeles Long Beach Captain of the Port Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce safety zones for annually reoccurring fireworks events taking place on July 4, 2026 in the Los Angeles—Long Beach Captain of the Port Zone. This action is necessary and intended to provide for the safety of life and property on the navigable waterways during these events. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any official patrol vessel.

**DATES:** The regulations in 33 CFR 165.1125 will be enforced on July 4, 2026 for the safety zones identified in the **SUPPLEMENTARY INFORMATION** section below for the times specified.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Lieutenant Commander Kevin Kinsella, U.S. Coast Guard Sector Los Angeles—Long Beach at telephone (310) 467–2099 or email *D11-SMB-SectorLALB-WWM@uscg.mil*.

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the safety zones in 33 CFR 165.1125 for the below listed events under Table 1 of § 165.1125, for the 2026 Fourth of July Fireworks Displays.

#### Item #2: LA County Dept of Beach and Harbors 4th of July Fireworks

- *Location:* Main Ship Channel of Marina del Rey, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone enforced from 8 p.m. to 10:30 p.m.

#### Item #3: Fourth of July Fireworks, City of Dana Point

- *Location:* Offshore Dana Point Harbor, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone enforced from 9 p.m. to 10:30 p.m.

#### Item #6: Fourth of July Fireworks, Emerald Bay Community Association.

- *Location:* Offshore Laguna Beach, CA.
- *Date:* July 4, 2026.

- *Time:* Safety zone enforced from 8:30 p.m. to 8:50 p.m.

**Item #8: Fourth of July Fireworks, Catalina Island CoC.**

- *Location:* Avalon Bay, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone will be enforced from 9 p.m. to 10 p.m.

**Item #9: Fourth of July Fireworks, City of Santa Barbara.**

- *Location:* Harbor Entrance of Santa Barbara, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone will be enforced from 9 p.m. to 10 p.m.

**Item #11: Fourth of July Fireworks, City of Redondo Beach.**

- *Location:* Offshore Redondo Beach, CA.
- *Date:* July 4, 2026.
- *Time:* Safety Zone will be enforced from 9 p.m. to 10:30 p.m.

**Item #13: Fourth of July Fireworks, City of Cayucos**

- *Location:* Cayucos Pier.
- *Date:* July 4, 2026.
- *Time:* Safety Zone will be enforced from 9:15 p.m. to 9:35 p.m.

During the enforcement periods, as reflected in Table 1 of § 165.1125, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any official patrol vessel.

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, marine information broadcasts, and a Marine Safety Information Bulletin.

If the Captain of the Port Los Angeles—Long Beach determines that the safety zone need not be enforced for the full duration stated in this notice, the Captain of the Port may use a Broadcast Notice to Mariners to reflect the change.

Dated: June 22, 2026

**Stacey L. Crecy,**

*Captain, U.S. Coast Guard, Captain of the Port, Los Angeles-Long Beach.*

[FR Doc. 2026-12932 Filed 6-25-26; 8:45 am]

**BILLING CODE 9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket Number USCG–2026–0818]

**RIN 1625-AA00**

**Safety Zone; Ohio River MM 602.0–605.0, Louisville, KY**

**AGENCY:** Coast Guard, Department of Homeland Security.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for navigable waters on the Ohio River from MM 602.0–605.0. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with an over water fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Ohio Valley, or their designated representative.

**DATES:** This rule is effective from 10:00 p.m. to 10:30 p.m. on June 27, 2026.

**ADDRESSES:** To view available documents go to <https://www.regulations.gov> and search for USCG–2026–0818.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, contact MST2 Shane Cuthrell, Sector Ohio Valley Waterways Management Division, U.S. Coast Guard; telephone 502–779–5348, or email [SECOHV-WWM@uscg.mil](mailto:SECOHV-WWM@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 and Authority**

The Coast Guard received notification that on June 27, 2026, fireworks will be launched from a barge on the Ohio River in the Louisville, KY waterfront area. The Captain of the Port (COTP), Ohio Valley has determined that potential hazards associated with fireworks are a safety concern for anyone within a mile of the fireworks display.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), 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 was notified of this event on June 12, 2026, but we must establish this safety zone by June 27, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

**III. Discussion of the Rule**

This rule establishes a safety zone from 10:00 p.m. to 10:30 p.m. on June 27, 2026. The safety zone will cover all navigable waters from mile markers 602.0–605.0 on the Ohio River. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port.

**IV. 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. Impact on Small Entities**

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 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.

**B. Collection of Information**

This rule will not call for a new collection of information under the