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1. Orthopaedic and Rehabilitation Devices Panel—Classification of Spinal Sphere Devices Meeting, December 12, 2013, available at <https://wayback.archive-it.org/7993/20170114044038/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM378083.pdf>.

List of Subjects in 21 CFR Part 888

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 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

- 1. The authority citation for part 888 continues to read as follows:

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

- 2. In § 888.3083, add paragraph (c) to read as follows:

§ 888.3083 Spinal spheres for use in intervertebral fusion procedures.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 30, 2025, for any spinal sphere for use in intervertebral fusion procedures as identified in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before October 30, 2025, been found to be substantially equivalent to any spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section, that was in commercial distribution before May 28, 1976. Any other spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: March 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06565 Filed 3–29–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2023–0259]

Safety Zone; Military Ocean Terminal Concord Safety Zone, Suisun Bay, Military Ocean Terminal Concord, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone in the navigable waters of Suisun Bay, off Concord, CA, in support of explosive on-loading to Military Ocean Terminal Concord (MOTCO) from March 30, 2023, through April 14, 2023. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The safety zone is open to all persons and vessels for transitory use, but vessel operators desiring to anchor or otherwise loiter within the safety zone must obtain the permission of the Captain of the Port San Francisco or a designated representative. All persons and vessels operating within the safety zone must comply with all directions given to them by the Captain of the Port San Francisco or a designated representative.

DATES: The regulations in 33 CFR 165.1198 will be enforced from 12:01 a.m. on March 30, 2023, until 11:59 p.m. on April 14, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant William Harris, Coast Guard Sector San Francisco, Waterways Management Division, 415–399–7443, SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1198 for the Military Ocean Terminal Concord, CA (MOTCO) regulated area from 12:01 a.m. on March 30, 2023, until 11:59 p.m. on April 14, 2023, or as announced via marine local broadcasts. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The regulation for this safety zone, § 165.1198, specifies the location of the safety zone which encompasses the navigable waters in the area between 500 yards of MOTCO Pier 2 in position 38°03'30" N, 122°01'14" W and 3,000 yards of the pier. During the enforcement periods, as reflected in

§ 165.1198(d), if you are the operator of a vessel in the regulated area you must comply with the instructions of the COTP or the designated on-scene patrol personnel. Vessel operators desiring to anchor or otherwise loiter within the safety zone must contact Sector San Francisco Vessel Traffic Service at 415–556–2760 or VHF Channel 14 to obtain permission.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via marine information broadcasts.

Dated: March 23, 2023.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2023–06613 Filed 3–29–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0928]

RIN 1625–AA00

Safety Zones; Coast Guard Sector Ohio Valley Annual and Recurring Safety Zones Update

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending and updating its safety zone regulations for annual events that take place in the Coast Guard Sector Ohio Valley area of responsibility (AOR). This action is necessary to update the current list of recurring safety zones with revisions, additional events, and removal of events that no longer take place in the Sector Ohio Valley. When these safety zones are enforced, certain restrictions are placed on marine traffic in specified areas.

DATES: This rule is effective on March 30, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0928 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 on this rule, call or email Petty Officer William Miller, Sector Ohio Valley, U.S. Coast Guard;