

States to consider and sign the updated standard MOU.

FDA is now extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that have not entered into a standard MOU with FDA until the effective date of a final rule regarding certain distributions of compounded human drug products under section 503A of the FD&C Act and publication of an updated standard MOU.¹

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2022-0870]

Special Local Regulations Northern California and Lake Tahoe Area Annual Marine Events; Sacramento Ironman Swim, Sacramento, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the annual Sacramento Ironman Triathlon marine event on October 23, 2022, to provide for the safety of life on navigable waterways in the Sacramento River during this event. Our regulation for marine events in Northern California identifies the regulated area for this event. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or loitering or anchoring in the regulated area, unless authorized by the designated Patrol Commander (PATCOM) or other Federal, State, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulations in 33 CFR 100.1103 will be enforced for the location listed in Table 1 to § 100.1103, Item number 5 from 6 a.m. to 10 a.m. on October 23, 2022.

¹ The Office of the Federal Register has published this document under the category "Rules and Regulations" pursuant to 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the legal content or intent of the document. See, 1 CFR 5.1(c).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony I. Solares, Sector San Francisco Waterways Management, U.S. Coast Guard; telephone 415-399-3585, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1103, Table 1 to § 100.1103, Item number 5 for the Sacramento Ironman Swim regulated area from 6 a.m. to 10 a.m. on October 23, 2022. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within Northern California, § 100.1103, specifies the location of the regulated area for the Sacramento Ironman Swim which encompasses portions of the American River and Sacramento River. During the enforcement period, the regulated area will be in effect in the navigable waters of the American River and Sacramento River from Township 9 Park to North of Tower Bridge.

During the enforcement period, under the provisions of 33 CFR 100.1103(b), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander (PATCOM) or any other Official Patrol, defined as a Federal, State, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. During the enforcement period, if you are the operator of a vessel that participates in the marine event within the regulated area, you must follow the route established by the marine event sponsor, and comply with directions from the Patrol Commander or other Official Patrol. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: October 17, 2022.

Jordan M. Balduenza,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0853]

RIN 1625-AA11

Safety Zone; Oil Pipeline Repairs, San Pedro Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the oil pipeline repair operations in the vicinity of a damaged pipeline, off the coast of Orange County and near San Pedro Bay, CA. The safety zone is necessary to reduce significant hazards to vessels, the harbor, and the public during ongoing pipeline repair. Entry of persons or vessels into this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port Sector Los Angeles—Long Beach, or his designated representative.

DATES: This rule is effective without actual notice from October 21, 2022 through December 24, 2022. For the purposes of enforcement, actual notice will be used from October 10, 2022, until October 21, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0853 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357-1603, email Maria.C.Wiener@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision