

Requirements.” Also include the FDA docket number found in brackets in the heading of this document.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 25, 2019 (84 FR 50566), FDA published a proposed rule that included an agency information collection assessment with a 60-day comment period to request comments on proposed requirements related to PMTA reporting and recordkeeping. In the **Federal Register** of November 26, 2019 (84 FR 65044), FDA published a document reopening the comment period on the proposed rule for an addition 20 days in response to multiple requests from commenters and the comment period closed on December 16, 2019.

FDA is reopening the comment period for the agency information collection activity associated with the proposed rulemaking for a period of 30 days, until April 9, 2020, to allow comment on an additional proposed form. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking.

FDA has included an additional proposed form (Form FDA 4057b) in the docket that will assist industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discusses bundled submissions in the proposed rule (84 FR 50566 at 50578) and notes that FDA intends to consider information on each tobacco product as a separate, individual PMTA. The form would assist applicants in

providing the unique identifying information for each product in a grouped submission of PMTAs that would be required by table 1 to 21 CFR 1114.7(c)(3)(iii) of the proposed rule (84 FR 50566 at 50637). By having the identifying information for products contained in a submission be more clearly organized, FDA will be able to more efficiently process and review the applications contained in a grouped submission.

FDA is revising table 22 from the Paperwork Reduction Act section contained in the proposed rule (84 FR 50566 at 50627) to add the associated burden for the additional proposed form. We estimate that 24 respondents will complete Form FDA 4057b for a total of 96 hours. Based on the Form FDA 4057 for use when submitting PMTA single and bundled submissions, FDA estimated that 24 respondents will submit PMTA bundles per year. Form FDA 4057b would be created once for each submission containing more than one PMTA. We assume the submitter could include from 2 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. If the data entry is automated, it could be performed more quickly. Assuming 4 hours per Form FDA 4057b for 24 applications, we estimate a total burden of 96 hours for this new activity. FDA does not believe the recordkeeping burden will be affected by the addition of the form.

The new total burden for the collections of information in this rulemaking are estimated to be 22,610 reporting hours and 52 recordkeeping hours for a total of 22,662 hours. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

Dated: March 4, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*  
[FR Doc. 2020–04828 Filed 3–9–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2020–0144

RIN 1625–AA00

#### Safety Zone; Cocos Lagoon, Merizo, GU

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary safety zone for navigable waters within Cocos Lagoon. This safety zone will encompass the designated swim course for the Cocos Crossing swim event in the waters of Cocos Lagoon, Merizo, Guam. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before April 9, 2020.

**ADDRESSES:** You may submit comments identified by docket number USCG–2020–0144 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Chief Petty Officer Robert Davis, Sector Guam, U.S. Coast Guard, by telephone at (671) 355–4866, or email at [WWMGuam@uscg.mil](mailto:WWMGuam@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, Purpose, and Legal Basis**

The Cocos Crossing swim event is a recurring annual event that occurs on the Sunday before Memorial Day. We have established safety zones for this swim event in past years.

The purpose of this rule is to ensure the safety of the participants and the navigable waters in the safety zone before, during, and after the scheduled swim event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

### III. Discussion of Proposed Rule

The Captain of the Port (COTP) is proposing to establish a safety zone from 6:00 a.m. to 1:00 p.m. on Sunday May 24, 2020 for the Cocos Crossing swimming event. This safety zone is necessary to protect all persons and vessels participating in this marine event from potential safety hazards associated with vessel traffic in the area. Race participants, chase boats, and organizers of the event will be exempt from the safety zone. Entry of persons or vessels into this safety zone is prohibited unless authorized by the COTP. The regulatory text we are proposing appears at the end of this document.

### IV. Regulatory Analyses

We developed this proposed 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, and we discuss First Amendment rights of protestors.

#### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of the Cocos Lagoon for approximately 7 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their

fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

#### C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

#### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and

Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

#### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves This proposed rule involves a safety zone lasting approximately 7 hours that would prohibit entry within 100-yards for swim participants. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without

jeopardizing the safety or security of people, places, or vessels.

## V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's Correspondence System of Records notice (84 FR 48645, September 26, 2018).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

### PART 165—SAFETY ZONE; COCOS LAGOON, MERIZO, GU

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 46 U.S.C. 70034; 46 U.S.C. 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14–0144 to read as follows:

### § 165.T14–0144 Safety Zone; Cocos Lagoon, Merizo, GU.

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70–15), all navigable waters within a 100-yard radius of race participants in Cocos Lagoon, Merizo, Guam. Race participants, chase boats and organizers of the event will be exempt from the safety zone.

(b) *Effective dates.* This rule is effective from 6 a.m. to 1 p.m. on May 24, 2020.

(c) *Regulations.* (1) In accordance with the general regulations in section § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or a designated on-scene representative.

(2) This safety zone is closed to all persons and vessel traffic, except as may be permitted by the COTP or a designated on-scene representative.

(3) The “on-scene representative” of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and Vessel operators desiring to enter or operate within the safety zone must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16 or at telephone number (671) 355–4821. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

(d) *Waiver.* The COTP may waive any of the requirements of this rule for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime security.

(e) *Penalties.* Vessels or persons violating this rule are subject to the penalties set forth in 46 U.S.C. 70036 (previously codified in 33 U.S.C. 1232) and 46 U.S.C. 70052 (previously codified in 50 U.S.C. 192).

Dated: March 5, 2020.

**Christopher M. Chase,**

*Captain, U.S. Coast Guard, Captain of the Port, Guam.*

[FR Doc. 2020–04806 Filed 3–9–20; 8:45 am]

**BILLING CODE 9110–04–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 9

[FRS 16536]

### Wireless E911 Location Accuracy Requirements

**AGENCY:** Federal Communications Commission.

**ACTION:** Petition for reconsideration.

**SUMMARY:** The Boulder Emergency Telephone Service Authority, on December 26, 2019, filed a Petition for Reconsideration in the Commission's Wireless E911 Location Accuracy rulemaking proceeding.

**DATES:** Oppositions to the Petition must be filed on or before March 25, 2020. Replies to the opposition must be filed on or before April 6, 2020.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** John Evanoff, Public Safety and Homeland Security Bureau, Policy and Licensing Division, at [john.evanoff@fcc.gov](mailto:john.evanoff@fcc.gov), or (202) 418–0848.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's document, released on February 26, 2020. The full text of this document is available for viewing and copying at the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. The full text of this document is also available online via the Commission's Electronic Comment Filing System at: <http://apps.fcc.gov/ecfs/>. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

*Subject.* Wireless E911 Location Accuracy Requirements, Report and Order, FCC 19–124, published at 85 FR 2660, January 16, 2020, in PS Docket No 07–114. This document is being published pursuant to 47 CFR 1.429(e). See also 47 CFR 1.4(b)(1) and 1.429(f), (g).

*Number of Petitions filed:* 1.

Federal Communications Commission.

**Marlene Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2020–04554 Filed 3–9–20; 8:45 am]

**BILLING CODE 6712–01–P**