

V. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. 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. 3501–3520). The collections of information in part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*, as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

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

■ 2. Add § 880.6210 to subpart G to read as follows:

§ 880.6210 Sharps needle destruction device.

(a) *Identification.* A sharps needle destruction device is a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

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

(1) Performance testing must demonstrate the following during operation of the device:

(i) The device safely contains or ventilates aerosols or fumes from device operation.

(ii) Excessive heat or sparks are not generated that may injure users or patients.

(iii) Simulated use testing must demonstrate sharps and/or needles are completely destroyed using a range of types and sizes of sharps sufficient to represent actual use.

(iv) Simulated use testing must demonstrate that the device is physically stable on the surface for which it is intended to be mounted to ensure the risk of harm to the patient/user as a result of the device falling is minimized.

(2) Validation of cleaning and disinfection instructions must demonstrate that the device can be safely and effectively reprocessed after use per the recommended cleaning and disinfection protocol in the instructions for use.

(3) Analysis and/or testing must validate electromagnetic compatibility and electrical safety, including the safety of any battery used in the device, under conditions which are consistent with the intended environment of device use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include:

(i) A clear description of the device and its technological features;

(ii) How the device is to be used, including validated cleaning and disinfection instructions;

(iii) Relevant precautions and warnings based on performance and in-use testing to ensure proper use of the device; and

(iv) Instructions to install device in adequately ventilated area and stable area.

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2017–0993]

RIN 1625–AA08

Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a recurring special local regulation for certain navigable waters of the Atlantic Ocean east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and extending north approximately six miles. The special local regulation is necessary to ensure the safety of the public, spectators, vessels, and the marine environment during aerobatic maneuvers conducted by high-speed, low-flying airplanes and high speed vessels performing inside of the regulated area during the Fort

Lauderdale Air Show. This special local regulation prohibits persons and non-participant vessels from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule is effective May 4, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2017–0993 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 Petty Officer Mara J. Brown, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email Mara.J.Brown@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 City of Fort Lauderdale notified the Coast Guard that it would be hosting the Fort Lauderdale Air Show annually over a Saturday and Sunday during the month of May. The regulated area would cover certain navigable waters of the Atlantic Ocean east of Fort Lauderdale, Florida beginning at Port Everglades Inlet and continuing north for approximately six miles.

In response, on January 25, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled “Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL” (83 FR 3450). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this event. During the comment period that ended February 26, 2018, we received 2 unrelated comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety dangers with aerial maneuvers conducted by

high speed, low-flying aircraft during air shows. The special local regulation is necessary to provide for the safety of event participants, spectators and vessels transiting in proximity to the event area.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Miami (COTP) has determined that potential hazards associated with the aerobatic and high speed aerial flight demonstrations demonstrated during the Ft. Lauderdale Air Show will be a safety concern for spectators and non-participant vessels in the regulated area. The purpose of this rule is to ensure the safety of vessels, persons, marine environment, and navigable waters in the regulated area before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received two comments on our NPRM published February 26, 2018. Both comments were unrelated to the regulation. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a special local regulation on certain waters of the Atlantic Ocean east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and continuing north for approximately six miles. The duration of the regulated area is intended to ensure the safety of the public during the aerial flight demonstrations and high speed boat races. Non-participant vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area without obtaining permission from the Captain of the Port (COTP) Miami or a designated representative. The Coast Guard will provide notice of the regulated area by Broadcast Notice to Mariners and on-scene designated representatives.

V. 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, 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 rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule 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 special local regulation. Vessel traffic will be able to safely transit around this regulated area, which will affect a small designated area of the Atlantic Ocean over a period of two days during the month of May. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners notifying the public of the regulated area via VHF-FM marine channel 16 and the rule would allow 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 received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will 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 V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to

the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 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.

C. Collection of Information

This rule will 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 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 rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 rule has implications for federalism or Indian tribes, please contact 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01, and Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined 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 rule involves a regulation that would prohibit persons and vessels from transiting the regulated area during the air show. This action is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A supplemental Environmental Assessment supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact 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.

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05-1.

■ 2. Add § 100.726 to read as follows:

§ 100.726 Special Local Regulation; Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL.

(a) *Location.* The following area is a regulated area located on the Atlantic Ocean in Fort Lauderdale, FL. All waters of the Atlantic Ocean encompassed within an imaginary line connecting the following points: Starting at Point 1 in position 26°11'01" N 080°05'42" W; thence due east to Point 2 in position 26°11'01" N 080°05'00" W; thence south west to Point 3 in position 26°05'42" N 080°05'35" W; thence west to Point 4 in position 26°05'42" N 080°06'17" W; thence following the shoreline north

back to the point of origin. These coordinates are based on North American Datum 1983.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Miami in the enforcement of the regulated area.

(c) *Regulations.* (1) All non-participant vessels or persons are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Miami by telephone at (305) 535-4472, or a designated representative via VHF-FM radio on channel 16 to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Miami or a designated representative.

(d) *Enforcement period.* This rule will be enforced annually on one weekend (Saturday and Sunday) during the month of May. The exact dates will be published annually in the **Federal Register** through a Notice of Enforcement. The Coast Guard may use Broadcast Notice to Mariners via VHF-FM channel 16 or on-scene designated representatives to notify the public of the exact dates and time of enforcement.

Dated: May 1, 2018.

M.M. Dean,

Captain, U.S. Coast Guard, Captain of the Port Miami.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2017-0993]

Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation for the Fort

Lauderdale Air Show from May 5 through 6, 2018 from 9:00 a.m. to 6:00 p.m., to provide for the safety of life on navigable waterways during this event. 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 displaying a Coast Guard ensign.

DATES: The special local regulation in 33 CFR 100.726 will be enforced from 9 a.m. until 6 p.m., each day from May 5, 2018, through May 6, 2018.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call Petty Officer Mara J. Brown, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305-535-4317, email Mara.J.Brown@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.726 for the Fort Lauderdale Air Show regulated area from 9:00 a.m. to 6:00 p.m. on May 5 and 6, 2018. This action is being taken to provide for the safety of life on navigable waterways during this 2-day event. Our regulation for the Fort Lauderdale Air Show, § 100.726, specifies the location of the regulated area for the Fort Lauderdale Air Show which is located on the Atlantic Ocean, east of Ft. Lauderdale, FL. During the enforcement periods, 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 displaying a Coast Guard ensign.

In addition to this notice 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 broadcasts.

Dated: May 1, 2018.

M.M. Dean,

Captain, U.S. Coast Guard, Captain of the Port Miami.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2017-1074]

Drawbridge Operation Regulation; San Leandro Bay, Between Alameda and Bay Farm Island, CA

AGENCY: Coast Guard, DHS.