

§ 558.485 [Amended]

■ 12. In paragraph (b)(3) of § 558.485, remove “021930” and in numerical sequence add “012286”.

§ 558.625 [Amended]

■ 13. In paragraphs (b)(10) and (b)(12) of § 558.625, remove “021930” and in its place add “No. 012286”.

§ 558.630 [Amended]

■ 14. In § 558.630, in paragraph (b)(2), remove “021930” and in its place add “012286; and in paragraph (b)(5), remove “021930” and in numerical sequence add “012286”.

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-14149 Filed 6-20-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. FDA-2008-N-0331]

Medical Devices; Change of Name; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to implement a nomenclature change and to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective June 23, 2008.

FOR FURTHER INFORMATION CONTACT: Paul S. Gadiock, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2343.

SUPPLEMENTARY INFORMATION:

I. Background

This document amends FDA's regulations to reflect a nomenclature change. It replaces the phrase “good manufacturing practice regulations” with the phrase “good manufacturing practice requirements of the quality system regulation” in 21 CFR parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these changes are nonsubstantive.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule makes only typographical and nonsubstantive changes in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PARTS 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892—[AMENDED]

■ 1. Parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended by removing the phrase “good manufacturing practice regulations” wherever it appears and by adding in its place the phrase “good manufacturing practice requirements of the quality system regulation”.

Dated: June 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-14153 Filed 6-20-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2008-0321]

Special Local Regulation; Thunderboat Regatta; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Thunderboat Regatta special local regulation in Fiesta Bay of Mission Bay, San Diego from 7:30 a.m. on September 19, 2008 through 5:30 p.m. on September 21, 2008. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other vessels and users of the waterway. During the enforcement period, no person or vessel may enter the special local regulation without permission of the Captain of the Port or his designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 7:30 a.m. on September 19, 2008 through 5:30 p.m. on September 21, 2008.

FOR FURTHER INFORMATION CONTACT: Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278-7233.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the Thunderboat Regatta in 33 CFR 100.1101 on September 19, 2008, from 7:30 a.m. to 5:30 p.m., September 20, 2008, from 7:30 a.m. to 5:30 p.m., and September 21, 2008, from 7:30 a.m. to 5:30 p.m.

Under the provisions of 33 CFR 100.1101, a vessel may not enter the regulated area, unless it receives permission from the COTP. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter in, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.1101(a) and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers. If the COTP or his designated representative determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: 8 June 2008.

C.V. Strangfeld,

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

[FR Doc. E8-14047 Filed 6-20-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2008-0399]

RIN 1625-AA00

Safety Zone; San Diego Symphony Orchestra; San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone, on the navigable waters of the San Diego Bay in support of the San Diego Symphony Opera fireworks display series. This temporary safety zone is necessary to provide for the safety of the crew, spectators, and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 9 p.m. on June 14, 2008 through 10 p.m. on August 31, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-0399 and are available online at <http://www.regulations.gov>. They are also available for inspection or copying two locations: The Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the U.S. Coast Guard Sector San Diego, 2710 N. Harbor Drive, San Diego, CA 92101 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278-7233. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The

logistical details of the fireworks show were not finalized nor presented to the Coast Guard in enough time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete.

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**. The issuance of the final approval and permitting was so recent that the rule would be made effective less than 30 days after publication. In addition, it would be contrary to the public interest not to publish this rule due to protection from inherent dangers to the crew and public that are present from a fireworks display.

Background and Purpose

The San Diego Symphony Orchestra and Copley Symphony Hall is sponsoring the San Diego Symphony Orchestra, which will include a fireworks presentation from a barge in the San Diego Bay. The barge will be located near the maritime navigational channel in the vicinity of North Embarcadero. The safety zone will be a 150 yard radius around the anchored firing barge. The sponsor will provide a chase boat to patrol the safety zone and inform vessels of the safety zone. This temporary safety zone is necessary to provide for the safety of the crew, spectators, and other vessels and users of the waterway.

Discussion of Rule

The Coast Guard is establishing a safety zone that would be effective from 9 p.m. to 10 p.m. on June 14, June 27-28, July 4-6, July 11-13, July 18-20, July 24-26, August 1-3, August 8-10, August 15-16, August 21-23, and August 29-31, 2008. The limits of the safety zone would be a 150 yard radius around the anchored firing barge located at approximately 32°42'12" N, 117°10'01" W.

The safety zone is necessary to provide for the safety of the crews, spectators, and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and