

competitors to enter the marketplace by lowering their costs. The Commissioner, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 1040913). Rather, the labeling statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

List of Subjects in 21 CFR Part 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

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

2. Section 878.5040 is added to subpart E to read as follows:

§ 878.5040 Suction lipoplasty system.

(a) *Identification.* A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

(b) *Classification.* Class II (special controls). Consensus standards and labeling restrictions.

Dated: February 5, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego, 98-001]

RIN 2115-AA97

Safety Zone: Colorado River, Bluewater Marina to La Paz County Park, Parker, AZ

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Colorado River beginning at Bluewater Marina in Parker, AZ, and extending approximately 10 miles south to La Paz County Park on the following dates: March 14, 1998 through March 15, 1998. The event requiring establishment of this safety zone is the Parker International Waterski Marathon.

The safety zone will consist of all navigable waters on the Colorado River extending approximately 10 miles south from Bluewater Marina in Parker, AZ, to Las Paz County Park. The safety zone is established to protect the lives and property of the event participants and spectators by establishing a safety zone around the entire event course. Entry into, transit through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port.

DATES: This temporary regulation becomes effective at 8 a.m. (PDT) on March 14, 1998, until 5 p.m. (PST) on March 14, 1998; then continues at 8 a.m. (PST) on March 15, 1998, until 5 p.m. (PST) on March 15, 1998.

ADDRESSES: Marine Safety Office San Diego, 2716 N. Harbor Drive, San Diego, CA 92101-1064.

FOR FURTHER INFORMATION CONTACT: Lieutenant Mike A. Arguelles, U.S. Coast Guard Marine Safety Office San Diego at (619) 683-6484.

SUPPLEMENTARY INFORMATION:

Regulatory Information

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good

cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of its effective date would be contrary to the public interest since the location of the Parker International Waterski Marathon, and other logistical details surrounding the event, were not finalized until a date fewer than 30 days prior to the event date.

Background and Purpose

The Parker International Waterski Marathon will consist of various waterski racing activities. The activities will take place from 8 a.m. (PST) until 5 p.m. each day from, and including, March 14, 1998 through, and including, March 15, 1998, in the navigable waters of the Colorado River, extending approximately 10 miles south from Bluewater Marina in Parker, AZ, to La Paz County Park. The race course will be marked by buoys and sponsor vessels to alert non-participants.

Discussion of Regulation

This regulation is necessary to protect the lives and property of the Parker International Waterski Marathon participants and spectators. The course is approximately 10 miles long and encompasses the entire water area on the Colorado River extending south from Bluewater Marina in Parker, AZ, to La Paz County Park. The course will be marked by buoys and sponsor vessels to alert non-participants.

On the following days and times, the course will be in use by vessels competing in the event: (1) March 14, 1998 through March 15, 1998, daily from 8:00 AM until 5:00 PM (PST). During these times, the Colorado River from Bluewater Marina in Parker, AZ, south to La Paz County Park, will be closed to all traffic with the exception of emergency vessels. No vessels other than participants, official patrol vessels, or emergency vessels will be allowed to enter into, transit through, or anchor within this zone unless specifically cleared by or through an official patrol vessel.

Regulatory Assessment

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that Order. It is not

significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR11040, February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of the Department of Transportation is unnecessary.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this regulation under the principles and criteria in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this regulation and concluded that under paragraph 2.B.2 of Commandant Instruction M16475.1B, this regulation is categorically excluded from further environmental documentation. This regulation is expected to have no significant effect on the environment. A Categorical Exclusion Determination and Environmental Analysis Checklist is available for inspection and copying in the docket to be maintained at the address listed under ADDRESSES in this preamble.

List of Subjects in 33 CFR Part 165

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

Regulation

In consideration of the foregoing, subpart F of part 165 of Title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for 33 CFR Part 165 continues to read as follows:

Part 165—[Amended]

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A temporary section 165.T–43 is added to read as follows:

§ 165.T11–043 Safety Zone: Colorado River, Bluewater Marina to La Paz County Park, Parker, AZ.

(a) *Location.* The following area constitutes a safety zone in the navigable waters of the Colorado River:

the entire water area of the Colorado River beginning at the Bluewater Marina in Parker, AZ, and extending approximately 10 miles south to La Paz County Part.

(b) *Effective Dates.* This regulation becomes effective at 8 a.m. (PDT) on March 14, 1998, until 5 p.m. (PST) on March 14, 1998; then continues at 8 a.m. (PST) on March 15, 1998, until 5 p.m. (PST) on March 15, 1998, unless canceled earlier by the Captain of the Port.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port.

Dated: January 30, 1998.

J.A. Watson, IV,

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

[FR Doc. 98–3913 Filed 2–13–98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Western Alaska 98–001]

RIN 2115–AA97

Safety Zone; Summer Bay, Unalaska Island, AK

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in Summer Bay, Unalaska Island, AK. The temporary zone is needed to protect the ongoing salvage operation of the M/V KUROSHIMA and the salvage vessel M/V AMERICAN SALVOR. Entry of vessels or persons into this zone not involved in the salvage operation is prohibited unless specifically authorized by the Captain of the Port.

DATES: This temporary rule becomes effective on January 26, 1998 at 1:00 p.m. ADT and terminates on 28 February 1998 at 11:59 p.m. ADT.

FOR FURTHER INFORMATION CONTACT: LCDR Rick Rodriguez, Chief of Port Operations, Coast Guard Captain of the Port Western Alaska, Anchorage, 510 L Street, Suite 100; Anchorage, Alaska 99501; (907) 271–6700.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The purpose of this temporary safety zone is to allow the salvage vessel to conduct salvage operations unencumbered by vessels at or

proceeding to anchor within the zone defined later in this rule.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent disruption of the safe salvage operation of the M/V KUROSHIMA.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federal Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under paragraph 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

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

For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; and 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; and 49 CFR 1.46.