day period ending February 26, 2001. FDA stated that the effective date of the direct final rule would be on June 11, 2001, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby will go into effect on June 11, 2001.

Dated: April 13, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–9873 Filed 4–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–777]

RIN 1218–AB36

Ergonomics Program

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule; removal.

SUMMARY: Under the Congressional Review Act, Congress has passed, and the President has signed, Public Law 107–5, a resolution of disapproval of OSHA's final Ergonomics Program Standard. OSHA published the ergonomics program standard on November 14, 2000 (65 FR 68262), and the standard became effective on January 16, 2001. Because Public Law 107–5 invalidates the standard, OSHA is hereby removing it from the Code of Federal Regulations.

DATES: This action is effective April 23, 2001.

FOR FURTHER INFORMATION CONTACT: OSHA Office of Information at (202)–693–1999.

SUPPLEMENTARY INFORMATION: On November 14, 2000, OSHA issued a final Ergonomics Program Standard (Subpart W of 29 CFR 1910) (65 FR 68262). The final rule became effective on January 16, 2001. On March 6, 2001 (Cong. Rec. p. S1887), the United States Senate passed a resolution of disapproval (S.J. Res. 6) of the Ergonomics Program Standard under the Congressional Review Act (5 U.S.C. 801 *et seq.*). The House of Representatives then passed S.J. Res. 6 on March 7, 2001 (Cong. Rec. p. H667). President Bush signed the resolution into law as Public Law 107–5 on March 20, 2001. Accordingly, OSHA is hereby removing the standard from the Code of Federal Regulations.

Authority: This document was prepared under the direction of R. Davis Layne, Acting Assistant Secretary for Occupational Safety and Health. It is issued under the authority of the Congressional Review Act (5 U.S.C. 801 *et seq.*), and Pub. L. 107–5 (March 20, 2001).

Signed at Washington, D.C. this 17 day of April, 2001.

R. Davis Layne,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

PART 1910—[AMENDED]

Accordingly, for the reasons set forth in the preamble, OSHA amends 29 CFR Part 1910 by removing Subpart W.

[FR Doc. 01–9957 Filed 4–20–01; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–00–242]

RIN 2115–AA97

Safety Zone: Macy's July 4th Fireworks, East River, NY

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a permanent safety zone for the annual Macy's July 4th fireworks display. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of the East River.

DATES: This rule is effective May 23, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–00–242) and are available for inspection or copying at Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, room 204, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4012.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 26, 2000, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone: Macy's July 4th Fireworks, East River, NY in the **Federal Register** (65 FR 81471). We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

The Coast Guard is establishing a permanent safety zone for the annual Macy's July 4th fireworks display in the East River. The safety zone encompasses all waters of the East River east of a line drawn from the Fireboat Station Pier, Battery Park City, in approximate position 40°42′15.4″ N 074°01′06.8″ W (NAD 1983) to Governors Island Light (2) (LLNR 35010), in approximate position 40°41′34.4″ N 074°01′10.9″ W (NAD 1983); north of a line drawn from Governors Island, in approximate position 40°41′25.3″ N 074°00′42.5″ W (NAD 1983) to the southwest corner of Pier 9A, Brooklyn; south of a line drawn from East 47th Street, Manhattan through the southern point of Roosevelt Island to 46 Road, Brooklyn, and all waters of Newtown Creek west of the Pulaski Bascule Bridge.

Vessels equal to or greater than 20 meters (65.6 feet) in length, carrying persons for the purpose of viewing the fireworks, may take position in an area inside the safety zone, at least 200 yards off the bulkhead on the west bank and just off the pierhead faces on the east bank of the East River between the Williamsburg Bridge and North 9th Street, Brooklyn. This area is bound by the following points: 40°42′45.5″ N 073°58′07.4″ W; thence to 40°42′50.4″ N 073°58′23.2″ W; thence to 40°43′23.1″ N 073°58′12.7″ W; thence to 40°43′21.5″ N 073°57′45.7″ W; (NAD 1983) thence back to the point of beginning. All vessels must be in this location by 6:30 p.m. (e.s.t.) the day of the event.

Once in position within the zone, all vessels must remain in position until released by the Captain of the Port, New York. On-scene-patrol personnel will monitor the number of designated vessels taking position in the viewing area of the zone. If it becomes apparent that any additional spectator vessels in the viewing area will create a safety hazard, the patrol commander may prevent additional vessels from entering it. After the event has concluded and the fireworks barges have safely relocated outside of the main channel, vessels will be allowed to depart the

viewing area as directed by the patrol commander.

We created the viewing area within this safety zone in order to reduce significant safety hazards in this area of the East River, due in great part, to the extremely strong currents. Based on experience from similar events in this area of the East River, we are concerned that smaller spectator craft located in between the two fireworks barge sites could drift into the fallout zone of either barge site. Additionally, experience from previous events has also shown that having large and small craft located in a confined area presents safety hazards for both sized vessels due to vessel wake, anchor swing radii, and restricted visibility of larger vessels in a confined area.

One safety zone is required for this large section of the East River because the Coast Guard has a limited amount of assets available to patrol this event. If we made this zone into two zones, we could not adequately enforce the boundaries of both zones, and the safety of the port and the mariners would be unacceptably compromised because of the two nearby fireworks barge locations in a confined waterway with significant currents. Fireworks barge locations are normally south of Roosevelt Island and the Brooklyn Bridge.

The Staten Island Ferries may continue services to their ferry slip at Whitehall Street, Manhattan. Continuing ferry services in the southwestern portion of the safety zone will not create a hazard nor be threatened by the fireworks display because Vessel Traffic Services New York will monitor and control the transits of these ferries. Failure to allow these continued ferry services will have a negative impact on residents of Staten Island, NY, and those persons traveling to and from Manhattan at the end of a national holiday.

The safety zone is effective from 6:30 p.m. (e.s.t.) until 11:30 p.m. (e.s.t.) on July 4th. If the event is cancelled due to inclement weather, then this safety zone is effective from 6:30 p.m. (e.s.t.) until 11:30 p.m. (e.s.t.) on July 5th. The safety zone prevents vessels from transiting this portion of the East River and is needed to protect boaters from the hazards associated with fireworks launched from 6 barges in the area. No vessel may enter the safety zone without permission from the Captain of the Port, New York.

This safety zone covers the minimum area needed and imposes the minimum restrictions necessary to ensure the protection of all vessels and the fireworks handlers aboard the barges.

Public notifications will be made prior to the event via the Local Notice to Mariners, marine information broadcasts, facsimile, and Macy's waterways telephone hotline. In previous years this telephone hotline has been established in early June.

The size of this safety zone was determined using National Fire Protection Association and New York City Fire Department standards for 8 to 12 inch mortars fired from a barge, combined with the Coast Guard's knowledge of tide and current conditions in this area. One safety zone is required for this large section of the East River because the Coast Guard has a limited amount of assets available to patrol this event. If we made this zone into two zones, we could not adequately enforce the boundaries of both zones, and the safety of the port and the mariners would be unacceptably compromised because of the two nearby fireworks barge locations in a confined waterway with significant currents.

Discussion of Comments and Changes

The Coast Guard received one letter commenting on the proposed rulemaking. No changes were made to this rulemaking. The commenter stated that the fireworks display will: (1) Emit thousands of pounds of air pollutants, some of which are the toxic combustion products of coloring agents used for the display; (2) be a violation of the Act to Prevent Pollution From Ships as it is an un-permitted discharge from the fireworks barges, including the discharge of plastics; (3) result in an adverse environmental impact due to the aggregation of spectator boats; and (4) require the Coast Guard to review its obligations for consistency review under the Coastal Zone Management Act.

The Coast Guard has determined that these matters are properly addressed in the determination whether to grant a marine event permit for the underlying fireworks event rather than in this rulemaking. It is the underlying event that triggers consideration of these items rather than this rulemaking itself. This rule, in accordance with our statutory authority, is limited to protecting safety of human life on the navigable waters during the event, which has not been approved yet. Prior to deciding whether to issue a marine event permit for this display, the Coast Guard will take these matters into account.

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. The Office of Management and Budget has not reviewed it 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).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

This safety zone temporarily closes a major portion of the East River to vessel traffic. There is a regular flow of traffic through this area; however, the impact of this regulation is expected to be minimal for the following reasons: the limited duration of the event; the extensive, advance advisories that will be made to allow the maritime community to schedule transits before and after the event; the event is taking place at a late hour on a national holiday; the event has been held for twenty-three years in succession and is therefore anticipated annually, small businesses may experience an increase in revenue due to the event; advance notifications will be made to the local maritime community by the Local Notice to Mariners, marine information broadcasts, facsimile, and the event sponsor establishes and advertises a telephone hotline which waterways users may call prior to the event for details of the safety zone. This telephone number will be published via the Local Notice to Mariners and facsimile. The number is normally activated in early June each year.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. 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 rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the East River during the times these zones are activated.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: the limited duration of the event; the extensive,

advance advisories that will be made to allow the maritime community to schedule transits before and after the event; the event is taking place at a late hour on a national holiday; the event has been held for twenty-three years in succession and is therefore anticipated annually, small businesses may experience an increase in revenue due to the event; advance notifications will be made to the local maritime community by the Local Notice to Mariners, marine information broadcasts, facsimile, and the event sponsor establishes and advertises a telephone hotline which waterways users may call prior to the event for details of the safety zone. This telephone number will be published via the Local Notice to Mariners and facsimile. The number is normally activated in early June each year.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. However, we received no requests for assistance from small entities.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

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.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes a safety zone. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

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 amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

2. Add § 165.166 to read as follows:

§ 165.166 Safety Zone: Macy's July 4th Fireworks, East River, NY.

(a) *Regulated Area.* The following area is a safety zone: All waters of the East River east of a line drawn from the Fireboat Station Pier, Battery Park City, in approximate position 40°42′15.4″ N 074°01′06.8″ W (NAD 1983) to Governors Island Light (2) (LLNR 35010), in approximate position 40°41′34.4″ N 074°01′10.9″ W (NAD 1983); north of a line drawn from Governors Island, in approximate position 40°41′25.3″ N 074°00′42.5″ W (NAD 1983) to the southwest corner of Pier 9A, Brooklyn; south of a line drawn from East 47th Street, Manhattan through the southern point of Roosevelt Island to 46 Road, Brooklyn, and all waters of Newtown Creek west of the Pulaski Bascule Bridge.

(b) *Activation period.* This section is activated annually from 6:30 p.m. until 11:30 p.m. on July 4th. If the event is cancelled due to inclement weather then this section is in effect from 6:30 p.m. until 11:30 p.m. on July 5th.

(c) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) No vessels, except the Staten Island Ferries, will be allowed to transit the safety zone without the permission of the Captain of the Port, New York.

(3) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

(4) Vessels equal to or greater than 20 meters (65.6 feet) in length, carrying persons for the purpose of viewing the fireworks, may take position in an area inside the safety zone, at least 200 yards off the bulkhead on the west bank and just off the pierhead faces on the east bank of the East River between the Williamsburg Bridge and North 9th Street, Brooklyn. This area is bound by the following points: 40°42′45.5″ N 073°58′07.4″ W; thence to 40°42′50.4″ N 073°58′23.2″ W; thence to 40°43′23.1″ N 073°58′12.7″ W; thence to 40°43′21.5″ N 073°57′45.7″ W; (NAD 1983) thence back to the point of beginning. All vessels must be in this location by 6:30 p.m. (e.s.t.) the day of the event.

Dated: April 11, 2001.

R.E. Bennis,

Rear Admiral, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 01–9990 Filed 4–20–01; 8:45 am]

BILLING CODE 4910–15–U