

frequency different than that required under this paragraph. The sponsor may also propose and adopt a different reporting format or frequency if the change is agreed to in advance by the director of the FDA review division that has responsibility for review of the IND.

(4) *Investigations of marketed drugs.* A sponsor of a clinical study of a drug marketed or approved in the United States that is conducted under an IND is required to submit IND safety reports for suspected adverse reactions that are observed in the clinical study, at domestic or foreign study sites. The sponsor must also submit safety information from the clinical study as prescribed by the postmarketing safety reporting requirements (e.g., §§ 310.305, 314.80, and 600.80 of this chapter).

(5) *Reporting study endpoints.* Study endpoints (e.g., mortality or major morbidity) must be reported to FDA by the sponsor as described in the protocol and ordinarily would not be reported under paragraph (c) of this section. However, if a serious and unexpected adverse event occurs for which there is evidence suggesting a causal relationship between the drug and the event (e.g., death from anaphylaxis), the event must be reported under § 312.32(c)(1)(i) as a serious and unexpected suspected adverse reaction even if it is a component of the study endpoint (e.g., all-cause mortality).

(d) *Followup.* (1) The sponsor must promptly investigate all safety information it receives.

(2) Relevant followup information to an IND safety report must be submitted as soon as the information is available and must be identified as such, i.e., "Followup IND Safety Report."

(3) If the results of a sponsor's investigation show that an adverse event not initially determined to be reportable under paragraph (c) of this section is so reportable, the sponsor must report such suspected adverse reaction in an IND safety report as soon as possible, but in no case later than 15 calendar days after the determination is made.

(e) *Disclaimer.* A safety report or other information submitted by a sponsor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the sponsor or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse event. A sponsor need not admit, and may deny, that the report or information submitted by the sponsor constitutes an admission that the drug caused or contributed to an adverse event.

■ 3. Section 312.64 is amended by revising paragraph (b) to read as follows:

§ 312.64 Investigator reports.

* * * * *

(b) *Safety reports.* An investigator must immediately report to the sponsor any serious adverse event, whether or not considered drug related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the drug caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the drug and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor. The investigator must record nonserious adverse events and report them to the sponsor according to the timetable for reporting specified in the protocol.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

■ 4. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

■ 5. Section 320.31 is amended in paragraphs (d)(1) and (d)(2) by removing the word "shall" and by adding in its place the word "must," and by removing "and" at the end of paragraph (d)(1) and replacing "this chapter." at the end of paragraph (d)(2) with "this chapter; and", and by adding paragraph (d)(3) to read as follows:

§ 320.31 Applicability of requirements regarding an "Investigational New Drug Application."

* * * * *

(d) * * *

(3) The person conducting the study, including any contract research organization, must notify FDA and all participating investigators of any serious adverse event, as defined in § 312.32(a), observed during the conduct of the study as soon as possible but in no case later than 15 calendar days after becoming aware of its occurrence. Each report must be submitted on FDA Form 3500A or in an electronic format that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files). Each report must bear prominent identification of its contents, i.e., "bioavailability/bioequivalence safety report." The person conducting the

study, including any contract research organization, must also notify FDA of any fatal or life-threatening adverse event from the study as soon as possible but in no case later than 7 calendar days after becoming aware of its occurrence. Each notification under this paragraph must be submitted to the Director, Office of Generic Drugs in the Center for Drug Evaluation and Research at FDA. Relevant followup information to a bioavailability/bioequivalence safety report must be submitted as soon as the information is available and must be identified as such, i.e., "Followup bioavailability/bioequivalence safety report." Upon request from FDA, the person conducting the study, including any contract research organization, must submit to FDA any additional data or information that the agency deems necessary, as soon as possible, but in no case later than 15 calendar days after receiving the request.

Dated: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-24296 Filed 9-28-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0620]

RIN 1625-AA00

Safety Zone: Monte Foundation Firework Display, Monterey, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of Monterey Bay off the fishing pier of Seacliff State Beach, Santa Cruz, CA in support of the Monte Foundation Firework Display. This safety zone is established to ensure the safety of participants and spectators from the dangers associated with the pyrotechnics. Unauthorized persons and vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission from the Captain of the Port or her designated representative.

DATES: This rule is effective from 7 a.m. through 9:30 p.m. on October 8, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0620 and are available online by going

to <http://www.regulations.gov>, inserting USCG-2010-0620 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Ensign Liz Ellerson, U.S. Coast Guard Sector San Francisco; telephone 415-399-7436, e-mail D11-PF-MarineEvents@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that it would be impracticable to publish a notice of proposed rulemaking (NPRM) with respect to this rule because the event would occur before the rulemaking process would be completed. Because of the dangers posed by the pyrotechnics used in this fireworks display, the safety zone is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

Basis and Purpose

The Monte Foundation Firework Display is scheduled to take place on October 8, 2010, on the navigable waters of Seacliff State Beach, in Monterey Bay, off of Santa Cruz, CA. The fireworks display is meant for entertainment purposes. This safety zone is issued to establish a temporary restricted area on the waters surrounding the fireworks launch site during loading of the pyrotechnics, and during the fireworks display. This restricted area around the launch site is necessary to protect spectators, vessels, and other property

from the hazards associated with the pyrotechnics on the fireworks barges. The Coast Guard has granted the event sponsor a marine event permit for the fireworks display.

Discussion of Rule

During the set up of the fireworks and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around the fireworks site within a radius of 100 feet. From 8:45 p.m. until 9:05 p.m., the area to which the temporary safety zone applies will increase in size to encompass the navigable waters around the fireworks site within a radius of 1,000 feet.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the fireworks site while the fireworks are set up, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels away from the immediate vicinity of the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes and executive orders.

Regulatory Planning and Review

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 Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have 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 may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of the areas off San Francisco, CA to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

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

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed

this rule under that Order and have determined that it does not have implications for federalism.

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.

Taking of Private Property

This rule will not cause 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 create 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of

energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded 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 is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves establishing, disestablishing, or changing Regulated Navigation Areas and security or safety zones. An environmental analysis checklist and a categorical exclusion determination are 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, and 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. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–359 to read as follows:

§ 165.T11–359 Safety zone; Monte Foundation Firework Display, Santa Cruz, CA

(a) *Location.* This temporary safety zone is established for the waters of Seacliff State Beach, in Monterey Bay, off of Santa Cruz, CA. The fireworks launch site will be located in position 36°58′11.20″ N, 121°54′36.79″ W (NAD 83). From 7 a.m. through 8:44 p.m., and from 9:06 p.m. until 9:30 p.m. on October 8, 2010, the temporary safety zone applies to the navigable waters around the fireworks site within a radius of 100 feet. From 8:45 p.m. until 9:05 p.m. the area to which the temporary safety zone applies will increase in size to encompass the navigable waters around the fireworks site within a radius of 1,000 feet.

(b) *Definitions.* As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general regulations in § 165.23 of this title, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP’s designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or through the 24-hour Command Center at telephone 415–399–3547.

(d) *Effective period.* This section is effective from 7 a.m. through 9:30 p.m. on October 8, 2010.

Dated: September 15, 2010.

C.L. Stowe,

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

[FR Doc. 2010-24364 Filed 9-28-10; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0138]

RIN 1625-AA00

Safety Zone; New York Air Show at Jones Beach State Park, Wantagh, NY

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a permanent safety zone for the annual New York Air Show at Jones Beach State Park in Wantagh, New York. This safety zone is necessary to provide for the safety of navigation and protection of the maritime public from the hazards inherent with an air show which consists of aircraft performing aerobatic maneuvers over the Atlantic Ocean off of Jones Beach State Park.

DATES: This rule is effective October 29, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2010-0138 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0138 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail: Petty Officer Joseph Graun, Prevention Department, USCG Sector Long Island Sound at 203-468-4459, e-mail: Joseph.L.Graun@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 21, 2010, we published a notice of proposed rulemaking (NPRM)

entitled: Safety Zone; New York Air Show at Jones Beach State Park, Atlantic Ocean off of Jones Beach, Wantagh, NY, in the **Federal Register** (75 FR 20802). We received no comments or requests for a public meeting on the proposed rule.

Basis and Purpose

The Air Show consists of aircraft performing aerobatics in close proximity to other aircraft over a specified area of the Atlantic Ocean off of Jones Beach State Park. The safety zone will provide for the safety of the maritime community and spectators viewing the Air Show from the water should an accident, such as a collision of aircraft, occur during the Show.

Entry into this zone is prohibited unless authorized by the Captain of the Port Long Island Sound or by Designated On-scene Patrol Personnel. Any violation of the safety zone described herein is punishable by, among other things, civil and criminal penalties, *in rem* liability against the offending vessel, and the initiation of suspension or revocation proceedings against Coast Guard-issued merchant mariner credentials.

Background

The New York State Office of Parks, Recreation and Historic Preservation sponsors an annual air show at Jones Beach State Park during the week before Memorial Day. In the past the Coast Guard established temporary regulations for this event every year and was not previously published in the CFR. The Notice of Proposed Rulemaking process provided the opportunity for public comments to be voiced and eliminated the unnecessary burden of establishing temporary rules every year.

Discussion of Comments and Changes

During the Notice of Proposed Rulemaking process, the sponsor of the event informed the Coast Guard that the dates of the enforcement period needed to be changed. The original proposed dates for the safety zone were from May 24, 2010 until May 30, 2010 allowing enforcement of the safety zone during the air show practice sessions. There will no longer be a practice session; therefore, the safety zone will only be needed during the main event on the Thursday through Sunday before Memorial Day in May.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses

based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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 Budget has not reviewed it under that Order.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have 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 may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in those portions of the Atlantic Ocean off of Jones Beach State Park, Jones Beach, New York covered by the safety zone.

This regulation may have some impact on the public, but the potential impact will be minimized for the following reasons: The zone would only be enforced for a temporary period each day over a four day period; and vessels may transit in all areas around the zone at all times.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), in the NPRM 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.

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-