

methods and models? For example, how can FDA support effective communication and coordination among all entities involved in the conduct of a trial to ensure a focus on the protection of human subjects and quality across the clinical trial process?

d. How should FDA focus its efforts in GCP regulations, policies, or practices to facilitate the use of technological advances, while maintaining the protection of research participants and the quality and integrity of data supporting regulatory decision-making?

IV. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-serve basis. Individuals who wish to attend the public hearing must register by sending an email to ClinTrialPublicMt@fda.hhs.gov on or before April 2, 2012, and provide complete contact information, including: Name, title, affiliation, address, email, and phone number. Those without email access may register by contacting Jennifer Hymiller (see **FOR FURTHER INFORMATION CONTACT**). Because seating is limited, FDA may limit the numbers of participants from each organization. Registrants will receive confirmation once they have been accepted for participation in the hearing. Onsite registration on the day of the hearing will be based on space availability on the day of the event starting at 7:30 a.m. If registration reaches maximum capacity, FDA will post a notice closing the meeting registration for the hearing at <http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm>.

Individuals who wish to present at the public hearing must register on or before April 2, 2012, through the email ClinTrialPublicMt@fda.hhs.gov, and state this intention on their notice of participation. You must provide complete contact information, including: Name, title, affiliation, address, email, and phone number. FDA has included questions for comment in section III of this document. You should identify the topic or section and the number of each question you wish to address in your presentation, so that FDA can consider that in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral

presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available a draft agenda on <http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm> approximately 2 weeks before the public hearing. Once FDA notifies registered presenters of their scheduled times, presenters should submit to electronic copy of their presentation to ClinTrialPublicMt@fda.hhs.gov on or before April 16, 2012.

If you need special accommodations because of disability, please contact Jennifer Hymiller (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live webcast of this public hearing can be viewed at the following Web address on the days of the public hearing: <http://www.fda.gov/Drugs/NewsEvents/ucm284118.htm>. A video record of the public hearing will be available at the same Web address for 1 year.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VII of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

VI. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.regulations.gov> approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD-ROM, upon submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: March 1, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-5476 Filed 3-6-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2012-0043]

RIN 1625-AA00

Safety Zone; Antique Boat Show, Niagara River, Grand Island, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on Niagara River, Grand Island, NY. This proposed rule is intended to restrict vessels from a portion of the Niagara River during the Antique Boat Show powerboat races. The safety zone established by this proposed rule is necessary to protect spectators, participants, and vessels from the hazards associated with powerboat races.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0043 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email LT Christopher Mercurio, Chief of Waterway Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9343, email SectorBuffaloMarineSafety@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0043), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or

mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the “submit a comment” box, which will then become highlighted in blue. In the “Document Type” drop down menu select “Proposed Rule” and insert “USCG–2012–0043” in the “Keyword” box. Click “Search” then click on the balloon shape in the “Actions” column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2012–0043” and click “Search.” Click the “Open Docket Folder” in the “Actions” column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request

for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Between 10 a.m. and 4 p.m. on Sept. 8, 2012, a series of hydroplane and power boat races will take place on the Niagara River near Grand Island, NY. The Captain of the Port Buffalo has determined that hydroplane racing presents significant hazards to public spectators and participants.

Discussion of Proposed Rule

This proposed temporary safety zone is necessary to ensure the safety of spectators and vessels during the Antique Boat Show.

The proposed safety zone will be effective and enforced from 9:30 a.m. until 4:30 p.m. on September 8, 2012.

The proposed safety zone will encompass all waters of Niagara River, Grand Island, NY starting at position 42°59′59″ N, 078°56′22″ W, East to 49°59′54″ N, 078°56′14″ W, South to 42°57′54″ N, 078°56′04″ W, West to 42°05′48″ N, 078°56′22″ W. (NAD 83)

Entry into, transiting, or anchoring within the proposed safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his on-scene representative. The Captain of the Port or his on-scene representative may be contacted via VHF Channel 16.

Regulatory Analyses

We developed this proposed 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 proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders.

It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security (DHS). We conclude that this proposed rule is not a significant regulatory action

because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this proposed rule will be relatively small and enforced for relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

Small Entities

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

This proposed temporary rule may affect the following entities, some of which might be small entities: the owners of operators of vessels intending to transit or anchor in a portion of the Niagara River near Grand Island, New York between 9:30 a.m. to 4:30 p.m. on September 8, 2012.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: this rule will be in effect for only a few hours and the safety zone will allow vessels to move freely around the safety zone on the Niagara River. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in

understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. 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 LT Christopher Mercurio, Chief of Waterway Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9343, email SectorBuffaloMarineSafety@uscg.mil. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed 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 proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. Because it involves the establishment of a safety zone.

An environmental analysis checklist and a preliminary categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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 proposes to amend 33 CFR parts 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; 46 U.S.C. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 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.T09-0043 to read as follows:

§ 165.T09-0043 Safety Zone; Antique Boat Show, Niagara River, Grand Island, NY.

(a) *Location.* The safety zone will encompass all waters of the Niagara River, Grand Island, NY starting at position 42°59'59" N, 078°56'22" W, East to 42°59'54" N 078°56'14" W, South to 42°57'54" N, 078°56'04" W, West to 42°05'48" N, 078°56'22" W. (NAD 83)

(b) *Effective and enforcement period.* This regulation is effective and will be enforced on September 8, 2012 from 9:30 a.m. until 4:30 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf. The on-scene representative of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: February 14, 2012.

S.M. Wischmann,

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

[FR Doc. 2012-5497 Filed 3-6-12; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2012-0095]

RIN 1625-AA00

Safety Zone; Virginia Beach Oceanfront Air Show, Atlantic Ocean, Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a safety zone on the navigable waters of the Atlantic Ocean in Virginia Beach, VA. This action is necessary to provide for the safety of life on navigable waters during the Virginia Beach Oceanfront Air Show. This action is intended to restrict vessel traffic movement to protect mariners from the hazards associated with air show events.

DATES: Comments and related material must be received by the Coast Guard on or before April 6, 2012.

ADDRESSES: You may submit comments identified by docket number USCG-2012-0095 using any one of the following methods:

(1) *Federal eRulemaking Portal:*
<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Christopher O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757-668-5581, email Christopher.A.ONeal@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2012-0095), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via <http://www.regulations.gov>) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at