

FDA is announcing the establishment of the Pediatric Advisory Committee by the Commissioner. The Best Pharmaceuticals for Children Act, as amended by the Pediatric Research Equity Act of 2003, provides for the establishment of this committee. This committee will provide advice and make recommendations to the Commissioner of Food and Drugs on matters relating to pediatric therapeutics, pediatric research, and any other matter involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The committee will also advise and make recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

The Pediatric Advisory Committee will be composed of a core of 12 voting members including the chair. Members and the chair are selected by the Commissioner of Food and Drugs (the Commissioner) or designee from among the authorities knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one member from a relevant patient or patient family organization and may include one technically qualified member, selected by the Commissioner or designee who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the committee may include one nonvoting member who is identified with industry interests and one nonvoting member who represents a pediatric health organization.

Therefore, the agency is amending 21 CFR 14.100(a) as set forth below.

#### List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

#### PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE:

■ 1. The authority citation for 21 CFR part 14 is revised to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42

U.S.C. 201, 262, 263b 264; Pub. L. 107–109; Pub. L. 108–155.

■ 2. Section 14.100 is amended by adding paragraph (a)(3).

#### § 14.100 List of standing advisory committees.

\* \* \* \* \*

(a) \* \* \*

(3) *Pediatric Advisory Committee.*

(i) Date established: June 18, 2004.

(ii) Function: Advises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility.

Dated: July 27, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD05–04–137]

RIN 1625–AA00

#### Safety Zone; Fireworks Display, Potomac River, Charles County, MD

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone on the waters of the Potomac River. This action is necessary to provide for the safety of life and property during a fireworks display on the Potomac River. The safety zone will allow for control of designated areas of the river and safeguard spectators and participants.

**DATES:** This rule is effective from 8 p.m. to 10:30 p.m. on August 14, 2004, with a rain date of August 28, 2004.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket CGD05–04–137 and are available for inspection or copying at Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, Maryland 21226–1791, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ronald Houck, Coast Guard Activities Baltimore, at (410) 576–2674.

**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. Publishing a NPRM and delaying its effective date would be contrary to public interest, since there is not sufficient time to publish a proposed rule in advance of the event and immediate action is needed to protect persons and vessels against the hazards associated with a fireworks display from a barge, such as premature detonation or falling burning debris.

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**. This safety zone of short duration is needed to provide for the safety of persons and vessels on the Potomac River and the public at large.

## Background and Purpose

On August 14, 2004, with a rain date of August 28, 2004, Crabmando Watersports Inc. in King George, Virginia, will sponsor an event that will include a fireworks display launched from a barge on the Potomac River. A fleet of spectator vessels is anticipated for these events. Due to the need for vessel control during the fireworks display, vessel traffic will be restricted to provide for the safety of spectators and transiting vessels.

The purpose of this regulation is to promote maritime safety, and to protect the environment and mariners transiting the area from the potential hazards due to a fireworks display from a barge. This rule establishes a safety zone on the waters of the Potomac River, enclosed within the arc of a circle with a radius of 600 feet and with its center located at position 38°20'30" N, 077°14'30" W.

## Discussion of Rule

The Coast Guard is establishing a safety zone on specified waters of the Potomac River. The safety zone will be in effect from 8 p.m. to 10:30 p.m. on August 14, 2004, with a rain date of August 28, 2004. This safety zone will protect spectators and mariners transiting the area from the potential hazards associated with a fireworks display launched from a barge on the Potomac River. This rule limits access to the safety zone to those vessels authorized by the Captain of the Port Baltimore. Except for persons or vessels authorized by the Captain of the Port Baltimore, no person or vessel may enter or remain in the zone. The Captain of the Port will notify the maritime

community via marine broadcasts of the safety zone.

### 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 Budget has not reviewed it under that Order. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security (DHS).

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

### 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 will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the Potomac River from 8 p.m. to 10:30 p.m. on August 14, 2004 or August 28, 2004 if the rain date becomes necessary. This rule 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 less than three hours late in the evening when vessel traffic is low, vessel traffic not constrained by its draft can pass safely around the safety zone, and the Coast Guard will issue maritime advisories to users of the river before the effective period.

### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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.

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).

### 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 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 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 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 Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section

2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This rule establishes a safety zone.

A final “Environmental Analysis Check List” and a final “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, 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 temporary § 165.T05–137 to read as follows:

#### § 165.T05–137 Safety zone; Fireworks Display, Potomac River, Charles County, Maryland.

(a) *Location.* The following area is a safety zone: All waters of the Potomac River, surface to bottom, enclosed within a 600 foot radius around the position 38°20′30″ N, 077°14′30″ W. All coordinates reference Datum NAD 1983.

(b) *Regulations.* All persons are required to comply with the general regulations governing safety zones in 33 CFR 165.23 of this part.

(1) All vessels and persons are prohibited from entering this zone, except as authorized by the Coast Guard Captain of the Port, Baltimore, Maryland.

(2) Persons or vessels requiring entry into or passage within the zone must request authorization from the Captain of the Port or his designated representative by telephone at (410) 576–2693 or by radio on VHF–FM channel 16.

(3) All Coast Guard assets enforcing this safety zone can be contacted on VHF marine band radio, channels 13 and 16.

(4) The operator of any vessel within or in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer

on board a vessel displaying a Coast Guard Ensign, and

(ii) Proceed as directed by any commissioned, warrant or petty officer on board a vessel displaying a Coast Guard Ensign.

(c) *Definitions.*

*Captain of the Port* means the Commander, Coast Guard Activities Baltimore or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(d) *Effective period.* This section is effective from 8 p.m. to 10:30 p.m. on August 14, 2004, with a rain date of August 28, 2004.

Dated: July 22, 2004.

**Jonathan C. Burton,**

*Commander, U.S. Coast Guard, Acting Captain of the Port, Baltimore, Maryland.*

[FR Doc. 04–17530 Filed 7–30–04; 8:45 am]

BILLING CODE 4910–15–P

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 165

[CGD05–03–116]

RIN 1625–AA87 (Formerly 1625–AA00)

#### Security Zone; Three Mile Island Generating Station, Susquehanna River, Dauphin County, PA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a security zone in the Captain of the Port, Philadelphia, PA zone, immediately adjacent to the nuclear power facility at Three Mile Island Generating Station. This zone is needed to ensure public safety and security from subversive or terrorist acts. This rule is intended to prevent future terrorist attacks against nuclear power facilities by denying entry into the zone unless authorized by the Captain of the Port or designated representative.

**DATES:** This rule is effective on August 1, 2004.

**ADDRESSES:** Comments and materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket CGD05–03–116, and are available for inspection or copying at Coast Guard Marine Safety Office Philadelphia, One Washington Avenue, Philadelphia, Pennsylvania 19147 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade Kevin Sligh or Ensign Jill Munsch, Coast Guard Marine Safety Office Philadelphia, at (215) 271–4889.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory History

On September 16, 2003, we published a notice of proposed rulemaking (NPRM) entitled “Security Zone; Three Mile Island Generating Station, Susquehanna River, Dauphin County, PA” in the **Federal Register** (68 FR 54177). We received one letter commenting on the proposed rule. The letter requested clarification on the coordinates of the proposed security zone.

In addition the following temporary final rule was published in the **Federal Register**:

“Security Zone; Three Mile Island Generating Station, Susquehanna River, Dauphin County, PA” (68 FR 33399, June 4, 2003). This temporary final rule established a security zone around the Three Mile Island Generating Station, Susquehanna River, Dauphin County, PA. The original effective date of the temporary final rule was to expire at 5 p.m. (EST) on January 24, 2004. The effective date has been extended through July 31, 2004 (69 FR 10616, March 8, 2004).

##### Background and Purpose

Terrorist attacks on September 11, 2001, inflicted catastrophic human casualties and property damage. These attacks highlighted the terrorists’ ability and desire to utilize multiple means in different geographic areas to increase their opportunities to successfully carry out their mission, thereby maximizing destruction using multiple terrorist acts.

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York, the Pentagon in Arlington, Virginia and Flight 93, the Federal Bureau of Investigation (FBI) has issued several warnings concerning the potential for additional terrorist attacks within the United States. The threat of maritime attacks is real as evidenced by the October 2002 attack on a tank vessel off the coast of Yemen and the prior attack on the USS COLE. These attacks manifest a continuing threat to U.S. assets as described in the President’s finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of the U.S. is endangered by the September, 11, 2001 attacks and that such disturbances continue to endanger the international relations of the United States. *See also Continuation of the National Emergency with Respect to*