

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2004-SW-14-AD. The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

#### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2004-15-21 **Agusta S.p.A.:** Amendment 39-13755. Docket No. 2004-SW-14-AD.

**Applicability:** Model A109K2 helicopters, with tail rotor trunnion assembly (trunnion), part number 109-0131-05 (all dash numbers), installed, certificated in any category.

**Compliance:** Required as indicated.

To detect a crack and prevent fatigue failure of the trunnion, loss of the tail rotor hub and blade assembly, and subsequent loss of control of the helicopter, do the following:

(a) Using a qualified Level II Inspector and following the Compliance Instructions, paragraphs 1. through 8., of Agusta Bollettino Tecnico No. 109K-37, dated February 13, 2004, dye penetrant inspect the trunnion for a crack as follows:

(1) Unless accomplished previously, within 10 hours time-in-service (TIS) for trunnions with 150 or more hours TIS;

(2) Unless accomplished previously, on or before accumulating 150 hours TIS for trunnions with less than 150 hours TIS; and

(3) Thereafter, at intervals not to exceed 150 hours TIS.

(b) If a crack is found, before further flight, replace the cracked trunnion with an airworthy trunnion before further flight.

(1) Within 5 days, report the part number, serial number, total hours TIS, and a description of the crack to Richard Monschke, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193-0110, telephone (817) 222-5116, fax (817) 222-5961.

(2) Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120-0056.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Safety Management Group, Rotorcraft Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) Do the inspection following Agusta Bollettino Tecnico No. 109K-37, dated February 13, 2004. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Agusta, 21017 Cascina Costa di Samarate (VA) Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605-222595. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/](http://www.archives.gov/federal_register/)

[code\\_of\\_federal\\_regulations/ibr\\_locations.html](#).

(e) This amendment becomes effective on August 17, 2004.

**Note:** The subject of this AD is addressed in Ente Nazionale per l'Aviazione Civile (Italy) AD No. 2004-068, dated February 18, 2004.

Issued in Fort Worth, Texas, on July 22, 2004.

**David A. Downey,**

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-17369 Filed 7-30-04; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 14

#### Advisory Committee; Pediatric Advisory Committee; Establishment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a Pediatric Advisory Committee in the Office of the Commissioner. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document requesting nominations for the membership on this committee. This document adds the Pediatric Advisory Committee to the agency's list of standing advisory committees in 21 CFR 14.100.

**DATES:** This rule is effective August 2, 2004. Authority for the committee being established will end on June 18, 2006, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Jan Johannessen, Office of Science and Health Coordination (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687.

**SUPPLEMENTARY INFORMATION:** Under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463) (5 U.S.C. app. 2); section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Public Law 101-635); section 14 of the Best Pharmaceuticals for Children Act (Public Law 107-109), as amended by section 3(b)(2) of the Pediatric Research Equity Act of 2003 (Public Law 108-155), and 21 CFR 14.40(b),

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.*

[FR Doc. 04–17543 Filed 7–29–04; 10:30 am]

**BILLING CODE 4160–01–S**

## 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