

environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the costs of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

### XIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects 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. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

### XIV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device;" the notice contains an analysis of the paperwork burden for the draft guidance.

### XV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposal. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

### XVI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Orthopedic and Rehabilitation Devices Panel Meeting Transcript, pp. 1–141, December 11, 2003.

### List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

### PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3080 is added to subpart D to read as follows:

#### § 888.3080 Intervertebral body fusion device.

(a) *Identification.* An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification.* (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 1, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6–1736 Filed 2–8–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[CGD05–06–006]

RIN 1625-AA08

#### Special Local Regulations for Marine Events; Maryland Swim for Life, Chester River, Chestertown, MD

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to amend the special local regulations at 33 CFR 100.533, established for the "Maryland Swim for Life" held annually on the waters of the Chester River, near Chestertown, Maryland by changing the event date to the third Saturday in June. This proposed rule is intended to restrict vessel traffic in portions of the Chester River and is necessary to provide for the safety of life on navigable waters during the event.

**DATES:** Comments and related material must reach the Coast Guard on or before April 10, 2006.

**ADDRESSES:** You may mail comments and related material to Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia

23704–5004, hand-deliver them to Room 119 at the same address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays, or fax them to (757) 398–6203. The Auxiliary and Recreational Boating Safety Branch, Fifth Coast Guard District, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the above address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dennis M. Sens, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

**SUPPLEMENTARY INFORMATION:**

**Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD05–06–006), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

**Public Meeting**

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the address listed under **ADDRESSES** explaining why one 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**

On June 17, 2006, the Maryland Swim for Life Association will sponsor the “Maryland Swim for Life”, an open water swimming competition held on the waters of the Chester River, near Chestertown, Maryland. Approximately 100 swimmers start from Rolph’s Wharf and swim up-river 2.5 miles then swim down-river returning back to Rolph’s Wharf. A fleet of approximately 20 support vessels accompanies the swimmers. The regulations at 33 CFR 100.533 are effective annually for the

Maryland Swim for Life marine event. Paragraph (d) of Section 100.533 establishes the enforcement date for the Maryland Swim for Life. This regulation proposes to change the enforcement date from the second Saturday in July to the third Saturday in June each year. Notice of exact time, date and location will be published in the **Federal Register** prior to the event. The Maryland Swim for Life Association who is the sponsor for this event intends to hold it annually. To provide for the safety of participants and support vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the swim.

**Discussion of Proposed Rule**

The Coast Guard proposes to amend the regulations at 33 CFR 100.533 by revising the date of enforcement in paragraph (d) to reflect the event will be conducted annually on the third Saturday in June. This proposed change is needed to accommodate attendance by a wide range of participants at the event. The special local regulations will be enforced from 6:30 a.m. to 1:30 p.m. on June 17, 2006, and will restrict general navigation in the regulated area during the swimming event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the effective period. The regulated area is needed to control vessel traffic during the event to enhance the safety of participants and transiting vessels.

**Regulatory Evaluation**

This proposed 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 proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. The effect of this proposed action merely establishes the dates on which the existing regulations would be in effect and modifies the boundaries of the regulated area and would not impose any new restrictions on vessel traffic.

**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 rule would effect 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 Chester River during the event.

This proposed rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This proposed rule would merely establish the dates on which the existing regulations would be in effect of the regulated area and would not impose any new restrictions on vessel traffic.

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 the address listed under **ADDRESSES**. 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 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 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

## Taking of Private Property

This proposed rule would 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 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 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 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)(h), of the Instruction, from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine event permit are specifically excluded from further analysis and documentation under that section.

Under figure 2–1, paragraph (34)(h), of the Instruction, an “Environmental Analysis Check List” and a “Categorical Exclusion Determination” are not required for this rule. Comments on this

section will be considered before we make the final decision on whether to categorically exclude this rule from further environmental review.

## List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

2. In § 100.533, revise paragraph (d), to read as follows:

#### § 100.533 Maryland Swim for Life, Chester River, Chestertown, Maryland.

\* \* \* \* \*

(d) *Enforcement period.* (1) This section will be enforced annually on the third Saturday in June. A notice of enforcement of this section will be published annually in the **Federal Register** and disseminated through the Fifth Coast Guard District Local Notice to Mariners announcing the specific event dates and times. Notice will also be made via marine Safety Radio Broadcast on VHF–FM marine band radio channel 22 (157.1 MHz).

(2) For 2006, this section will be enforced from 6:30 a.m. to 1:30 p.m. on June 17, 2006.

Dated: January 23, 2006.

**Larry L. Hereth,**

*Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[CGD05–06–007]

RIN 1625–AA08

#### Special Local Regulations for Marine Events; Severn River, College Creek, Weems Creek and Carr Creek, Annapolis, MD

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to suspend the special local regulations at