

raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received on this companion proposed rule will also be treated as comments on the direct final rule. We will not provide additional opportunity for comment.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this companion proposed rule. Instead, we will publish a document confirming the effective date within 30 days after the comment period ends, and we intend the direct final rule to become effective 30 days after publication of the confirmation notice.

If FDA receives any significant adverse comments, the Agency will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures. The Agency will address the comments in a subsequent final rule.

A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466). The guidance document may be accessed at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

### III. Analysis of Impacts

HHS/FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563

direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, 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 under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule imposes no duties or obligations on small entities, the Agency proposes to certify that the final rule would 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 \$136 million, using the most current (2010) 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.

### IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

#### List of Subjects

21 CFR Part 21

Privacy.

45 CFR Part 5b

Privacy.

Therefore, the Department of Health and Human Services is proposing to amend 21 CFR part 21 and 45 CFR part 5b to read as follows:

### Title 21

#### PART 21—PROTECTION OF PRIVACY

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

**Authority:** 21 U.S.C. 371; 5 U.S.C. 552, 552a.

2. Section 21.61 is amended by adding paragraph (d) to read as follows:

#### § 21.61 Exempt systems.

\* \* \* \* \*

(d) Records in the following Food and Drug Administration Privacy Act Records Systems are exempt under 5 U.S.C. 552a(k)(2) and (k)(5) from the provisions enumerated in paragraph (a)(1) through paragraph (a)(3) of this section: FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09–10–0020.

### Title 45

#### PART 5b—PRIVACY ACT REGULATIONS

3. The authority citation for 45 CFR part 5b continues to read as follows:

**Authority:** 5 U.S.C. 301, 5 U.S.C. 552a.

4. Section 5b.11 is amended by adding paragraph (b)(2)(vii)(C) to read as follows:

#### § 5b.11 Exempt systems.

\* \* \* \* \*

(b) \* \* \*  
(2) \* \* \*  
(vii) \* \* \*

(C) FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC.

\* \* \* \* \*

Dated: July 20, 2012.

**Kathleen Sebelius,**

*Secretary of Health and Human Services.*

[FR Doc. 2012–20890 Filed 8–27–12; 8:45 am]

**BILLING CODE 4160–01–P**

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG–2012–0594]

RIN 1625–AA08

#### Special Local Regulation for Marine Events; Temporary Change of Dates for Recurring Marine Events in the Fifth Coast Guard District, Poquoson Seafood Festival Workboat Races, Back River; Poquoson, VA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to temporarily change the enforcement period of special local regulations for one recurring marine event in the Fifth Coast Guard District. This event is the Poquoson Seafood Festival Workboat Race, which includes a series of boat races to be held on the waters of Back River, Poquoson, Virginia. These special local regulations are necessary to provide for the safety of life on navigable waters during the events. This action is intended to restrict vessel traffic during the power boat races on the Back River in the vicinity of Messick Point, in Poquoson, Virginia.

**DATES:** Comments and related material must be received by the Coast Guard on or before September 15, 2012.

**ADDRESSES:** You may submit comments identified by docket number USCG–2012–0594 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 Hector Cintron, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757–668–5581, email [Hector.L.Cintron@uscg.mil](mailto:Hector.L.Cintron@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:**

##### **Table of Acronyms**

DHS Department of Homeland Security  
FR **Federal Register**  
NPRM Notice of Proposed Rulemaking

##### **A. 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.

##### **1. Submitting Comments**

If you submit a comment, please include the docket number for this rulemaking, 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 at <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, 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>, type the docket number (USCG–2012–0594) in the “SEARCH” box and click “SEARCH.” Click on “Submit a Comment” on the line associated with this rulemaking.

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.

##### **2. 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>, type the docket number (USCG–2012–0594) in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. 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.

##### **3. 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).

##### **4. 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**.

##### **B. Regulatory History and Information**

This rule involves an annually occurring marine event that takes place on the 2nd Sunday in October, as published in table to 33 CFR 100.501. The City of Poquoson has requested that the enforcement dates be changed for this year’s event.

##### **C. Basis and Purpose**

The City of Poquoson sponsors an annual workboat race which takes place on the navigable waters of the Back River in Poquoson, Virginia. This event occurs in connection with the city’s annual seafood festival. A special local regulation is effective annually to create a safety zone for the workboat races.

The regulation listing annual marine events within the Fifth Coast Guard District and corresponding dates is 33 CFR 100.501. The Table to § 100.501 identifies marine events by Captain of the Port zone. This particular marine event is listed in section (c.), line No. 19 of the table.

The current regulation described in section (c.) line No. 19 of the table indicates that the workboat race event should take place this year on October 7, 2012 (the Second Sunday in October). This regulation proposes to change the date for the event to take place on September 30, 2012 for this year only.

A fleet of spectator vessels is expected to gather near the event site to view the competition. To provide for the safety of the participants, spectators and other transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area. The regulated area as described in 33 CFR 100.501 will be enforced from 1 p.m. to 4 p.m. September 30, 2012, or, in the case of inclement weather, from 1 p.m. to 4

p.m. on October 7, 2012. During this enforcement period, vessels may not enter or remain in the regulated area unless they receive permission from the Coast Guard Patrol Commander.

#### D. Discussion of Proposed Rule

The Coast Guard proposes to temporarily suspend the regulation listed at section (c.) line No. 19 in the Table to § 100.501 and insert this new temporary regulation at the Table to § 100.501 line No. 25 in order to reflect the change of date for this year's event. This change is needed to accommodate the change in date of the annual Seafood Festival Workboat Race Event. No other portion of the Table to § 100.501 or other provisions in § 100.501 shall be affected by this regulation.

This special local regulation will restrict vessel movement in the regulated area during the marine event. The regulated area is needed to control vessel traffic and enhance the safety of participants and spectators of the Poquoson Seafood Festival Workboat Race. The regulation will be enforced from 1 p.m. to 4 p.m. on September 30, 2012 or if necessary due to inclement weather from 1 p.m. to 4 p.m. on October 7, 2012. 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.

In addition to notice in the **Federal Register**, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, and marine information broadcasts

#### E. Regulatory Analyses

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

##### 1. 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 Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

Although this rule prevents traffic from transiting a portion of certain waterways during specified events, the effect of this regulation will not be

significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, local radio stations and area newspapers so mariners can adjust their plans. Additionally, this rulemaking does not change the permanent regulated areas that have been published in 33 CFR § 100.501, Table to § 100.501.

##### 2. Impact on 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.

The rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in this section of the Back River during the event from 1 p.m. to 4 p.m. on September 30, 2012.

Although this regulation prevents traffic from transiting a portion of the Back River during the event, this rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would be in effect for only a limited period. Vessel traffic will be able to transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so. Before the enforcement period, the Coast Guard will issue maritime advisories so mariners can adjust their plans accordingly.

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.

##### 3. 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. 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 person listed in the **FOR FURTHER INFORMATION CONTACT**, above. 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.

##### 4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

##### 5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

##### 6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

##### 7. 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

##### 8. 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.

9. 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.

10. Protection of Children From Environmental Health Risks

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.

11. 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.

12. Energy Effects

This proposed rule is not a "significant energy action" under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use 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.

13. Technical Standards

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

14. 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 which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(h), of the Instruction. This rule involves implementation of regulations within 33 CFR Part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative

impact on the safety or other interest of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, and sail board racing. Under figure 2-1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under ADDRESSES.

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.

2. In § 100.501, in the Table to § 100.501, temporarily suspend line (c)19.

3. In § 100.501, in the Table to § 100.510, add temporary line 23 to read as follows:

§ 100.501 Special Local Regulations; Marine Events in the Fifth Coast Guard District.

\* \* \* \* \*

(C.) COAST GUARD SECTOR HAMPTON ROADS—COTP ZONE

Table with 5 columns: No., Date, Event, Sponsor, Location. Row 23: September 30, 2012 or in the case of inclement weather October 7, 2012. Poquoson Seafood Festival Workboat Races. City of Poquoson. The waters of the Back River, Poquoson, Virginia, bounded on the north by a line drawn along latitude 37°06'30" N, bounded on the south by a line drawn along latitude 37°06'15" N, bounded on the east by a line drawn along longitude 076°18'52" W and bounded on the west by a line drawn along longitude 076°19'30" W.

Dated: August 1, 2012. John K. Little, Captain, U.S. Coast Guard, Captain of the Port Hampton Roads. [FR Doc. 2012-21211 Filed 8-27-12; 8:45 am] BILLING CODE 9110-04-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH-2011-0001]

Privacy Act; Implementation

AGENCY: Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), is implementing a new system of records, 09-25-0223, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH." HHS is exempting this system of records from certain requirements of the Privacy Act to protect the integrity of NIH research misconduct proceedings and to protect the identity of confidential sources in