residential through-the-fence access and invited comments.

There was an inadvertent omission in the Notice which FAA is correcting through this amendment. In the Addresses paragraph, the FAA inadvertently omitted the applicable Department of Transportation Docket Number.

Correction

In the document published on July 30, 2012 (77 FR 44515) FR Doc. 2010–18058, on page 44515 in column 3, under the heading **ADDRESSES** paragraph of this document, replace ''Docket Number FAA–2012–XXX'' with ''Docket Number FAA–2012–0754''.

Extension of Time To Comment

The Experimental Aircraft Association requested the FAA extend the comment period an additional two weeks. The FAA believes this is a reasonable request and hereby extends the comment period to September 14, 2012.

Dated: Issued in Washington, DC, on August 22, 2012.

Randall S. Fiertz,

Director, Airport Compliance and Management Analysis.

[FR Doc. 2012–21147 Filed 8–27–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 21

[Docket No. FDA–2011–N–0252]

Office of the Secretary

45 CFR Part 5b

Privacy Act, Exempt Record System

AGENCY: Office of the Secretary, Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) will be implementing a new system of records, 09–10–0020, ''FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC.'' HHS/FDA proposes to exempt this system of records from certain requirements of the Privacy Act to protect the integrity of FDA's scientific misconduct inquiries and investigations and to protect the identity of confidential sources in such investigations.

DATES: Submit either electronic or written comments by November 13, 2012. If HHS/FDA receives any significant adverse comments, the Agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. HHS/FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0252, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (For paper or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Frederick Sadler, Division of Freedom of Information, Office of Public Information & Library Services, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–8975, *Frederick.Sadler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is implementing a new system of records called the ''FDA Records Related to Research Misconduct Proceedings.'' The purpose of this system of records is to implement FDA's responsibilities for addressing research integrity and misconduct, in accordance with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR part 93), for research performed by persons who are FDA employees, agents of the Agency, or who are affiliated with the Agency by contract or agreement. The term ''research misconduct'' is defined at 42 CFR 93.103 to mean ''fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.'' The general policy of the PHS Policies on Research Misconduct is that ''Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds.'' (42 CFR 93.100(a)). The PHS Policies on Research Misconduct provide for a number of HHS administrative actions that can be taken in response to a research misconduct proceeding, such as the suspension of a contract, debarment, or an adverse personnel action against a Federal employee (42 CFR 93.407). In addition, under 42 CFR 93.401, FDA shall at any time during a research misconduct proceeding notify HHS' Office of Research Integrity (ORI) immediately to ensure that FDA's Office of Criminal Investigations, HHS Office of Inspector General, the Department of Justice, or other appropriate law enforcement Agencies, are notified if there is a reasonable indication of possible violations of civil or criminal law.

FDA's new system of records will be modeled after the system of records maintained by ORI, entitled ''HHS Records Related to Research Misconduct Proceedings, HHS/OPHS/ORI'' System No. 09–37–0021 (59 FR 36717, July 19, 1994; revised most recently at 75 FR 44847, August 31, 2009).

FDA's scientific misconduct inquiry and investigation records are located in the Office of the Chief Scientist in FDA's Office of the Commissioner. FDA is preparing to organize and operate these records as a ''system of records'' as that term is defined by the Privacy Act. FDA is publishing a System of Records Notice (SORN) for this system in the **Federal Register** contemporaneous with publication of this proposed rule.

Under the Privacy Act (5 U.S.C. 552a), individuals have a right of access to information pertaining to them which is contained in a system of records. At the same time, the Privacy Act permits certain types of systems to be exempt

from some of the Privacy Act requirements. For example, section 552a(k)(2) of the Privacy Act allows Agency heads to exempt from certain Privacy Act provisions a system of records containing investigatory material compiled for law enforcement purposes. This exemption's effect on the record access provision is qualified in that if the maintenance of the material results in the denial of any right, privilege, or benefit that the individual would otherwise be entitled to by Federal law, the individual must be granted access to the material except to the extent that the access would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence. In addition, section 552a(k)(5) of the Privacy Act permits an Agency to exempt investigatory material from certain Privacy Act provisions where such material is compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

As stated previously in this document, FDA may take administrative action in response to a research misconduct proceeding and, where there is a reasonable indication that a civil or criminal fraud may have taken place, will refer the matter to the appropriate investigative body. As such, FDA scientific misconduct inquiry and investigative files are records compiled for law enforcement purposes, and the subsection (k)(2) exemption is applicable to this system of records. Moreover, where misconduct inquiry and investigative files are compiled solely for the purpose of making determinations as to the suitability for appointment as special Government employees or eligibility for Federal contracts from PHS Agencies, the subsection (k)(5) exemption is applicable.

HHS/FDA is therefore proposing to exempt this system under subsections (k)(2) and (k)(5) of the Privacy Act from the notification, access and amendment provisions of the Act (subsections (c)(3), (d)(1) to (d)(4), (e)(4)(G) and (e)(4)(H), and (f)). As described in the following paragraphs, the exemptions are necessary in order to maintain the integrity of the research misconduct proceedings and to ensure that FDA's efforts to obtain accurate and objective information will not be hindered. However, consideration would be given to requests for notification, access, and amendment that are addressed to FDA's Research Integrity Officer (System Manager) or Privacy Act Coordinator. The specific rationales for applying each of these exemptions are as follows:

- *Subsection (c)(3).* An exemption from the requirement to provide an accounting of disclosures is needed during the pendency of a research misconduct proceeding. Release of an accounting of disclosures to an individual who is the subject of a pending research misconduct assessment, inquiry or investigation could prematurely reveal the nature and scope of the assessment, inquiry or investigation and could result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding.
- *Subsection (d)(1).* An exemption from the access requirement is needed both during and after a research misconduct proceeding, to avoid revealing the identity of any source who was expressly promised confidentiality. Only material that would reveal a confidential source will be exempt from access. Protecting the identity of a source is necessary when the source is unwilling to report possible research misconduct because of fear of retaliation (e.g., from an employer or coworkers).
- *Subsections (d)(2) through (d)(4).* An exemption from the amendment provisions is necessary while one or more related research misconduct proceedings are pending. Allowing amendment of investigative records in a pending proceeding could interfere with that proceeding; even after that proceeding is concluded, an amendment could interfere with other pending or prospective research misconduct proceedings, or could significantly delay inquiries or investigations in an attempt to resolve questions of accuracy, relevance, timeliness, and completeness.
- *Subsection (e)(4)(G) and (e)(4)(H).* An exemption from the notification provisions is necessary during the pendency of a research misconduct proceeding, because notifying an individual who is the subject of an assessment, inquiry, or investigation of the fact of such proceedings could prematurely reveal the nature and scope of the proceedings and result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding.
- *Subsection (f).* An exemption from the requirement to establish procedures for notification, access to records, amendment of records, or appeals of denials of access to records, is appropriate because the procedures would serve no purpose in light of the other exemptions, to the extent that those exemptions apply.

As stated previously in this document, FDA's new system of records will be modeled after the system of records maintained by ORI. ORI has exempted these records under subsections (k)(2) and (k)(5) of the Privacy Act from the notification, access, accounting, and amendment provisions of the Privacy Act, to ensure that these records will not be disclosed inappropriately (59 FR 36717, July 19, 1994). Likewise, FDA believes that exempting the new system, ''FDA Records Related to Research Misconduct Proceedings, HHS/FDA,'' from the same Privacy Act provisions is essential to ensure that material in FDA's files related to research misconduct proceedings is not disclosed inappropriately. Except for information that would reveal the identity of a source who was expressly promised confidentiality, the access exemption will not prohibit HHS/FDA from granting respondents' access requests consistent with the PHS Policies on Research Misconduct (42 CFR Part 93), including in those cases in which a finding of research misconduct has become final and an administrative action has been imposed.

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework to proceed with standard notice-and-comment rulemaking if the direct final rule receives significant adverse comment and is withdrawn. FDA is publishing the direct final rule because we believe the rule is noncontroversial and we do not anticipate receiving any significant adverse comments.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment

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.