

requirement does not apply if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities” (5 U.S.C. 603). This rule removes one section from Title 14 of the CFR and, therefore, does not have a significant economic impact on a substantial number of small entities.

#### *Review Under the Paperwork Reduction Act*

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *Review Under EO 13132*

EO 13132, “Federalism,” 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any substantial direct effects on state and local governments within the meaning of the EO. Therefore, no Federalism assessment is required.

#### **List of Subjects in 14 CFR Part 1204**

Authority delegations.

Accordingly, under the authority of the National Aeronautics and Space Act, as amended, NASA amends 14 CFR part 1204 as follows:

#### **PART 1204—ADMINISTRATIVE AUTHORITY AND POLICY**

- 1. The authority citation for part 1204 subpart 500 is revised to read as follows:

Authority: 51 U.S.C. 20113.

#### **§ 1204.506 [Removed and Reserved]**

- 2. Remove and reserve § 1204.506.

**Charles F. Bolden, Jr.,**

*Administrator.*

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#### **NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

#### **14 CFR Part 1212**

[Document No. NASA—NASA-2012-0005]

RIN 2700-AD86

#### **Update of Existing Privacy Act—NASA Regulations**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Direct final rule.

**SUMMARY:** This rule makes non-substantive changes to NASA rules governing implementation of the Privacy Act by updating statute citations, position titles, terminology, and adjusting appellate responsibility for records held by the NASA Office of the Inspector General. This revision is part of NASA’s retrospective plan under EO 13563 completed in August 2011. NASA’s full plan can be accessed on the Agency’s open Government Web site at <http://www.nasa.gov/open/>.

**DATES:** This rule is effective on December 3, 2012, unless adverse comments are received by November 5, 2012. If adverse comments are received, NASA will publish a timely withdrawal of the rule in the **Federal Register**.

**ADDRESSES:** Comments must be identified with RIN 2700-AD86 and may be sent to NASA via the *Federal E-Rulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitted comments. Please note that NASA will post all comments on the Internet with changes, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Patti Stockman, Office of the Chief Information Officer, 202-358-4787.

#### **SUPPLEMENTARY INFORMATION:**

#### **Direct Final Rule Adverse Comments**

NASA has determined this rulemaking meets the criteria for a direct final rule because it involves nonsubstantive changes to remove sections from the Code of Federal Regulations that are obsolete and no longer used. No opposition to the changes and no significant adverse comments are expected. However, if the Agency receives a significant adverse comment, it will withdraw this direct final rule by publishing a notice in the **Federal Register**. A significant adverse comment is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule’s underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

#### **Background**

This rule was last published in the **Federal Register** as an interim final rule (FR 57 4928) on February 11, 1992. That revision changed internal Agency responsibility with regard to the handling of appeals, set forth general

housekeeping policies and procedures, and made changes to comply with statutory requirements.

#### **Statutory Authority**

The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20101(a), authorizes the NASA Administrator to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

#### **Regulatory Analysis**

*Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improvement Regulation and Regulation Review*

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as “not significant” under section 3(f) of Executive Order 12866.

#### *Review Under the Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities” (5 U.S.C. 603). This rule does not have any economic impact on small entities.

#### *Review Under the Paperwork Reduction Act*

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *Review Under Executive Order of 13132*

Executive Order 13132, “Federalism,” 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any

direct effects on state and local governments within the meaning of the Executive Order. Therefore, no Federalism assessment is required.

#### List of Subjects in 14 CFR Part 1212

Privacy, Procedural rules.

Accordingly, NASA amends 14 CFR part 1212 as follows:

### PART 1212—PRIVACY ACT—NASA REGULATIONS

■ 1. The authority citation for part 1212 is revised to read as follows:

**Authority:** The National Aeronautics and Space Act, as amended, 51 U.S.C. 20101 *et seq.*; the Privacy Act of 1974, as amended, 88 Stat. 1896, 5 U.S.C. 552a.

#### § 1212.100 [Amended]

■ 2. Section 1212.100 is amended by removing the words “NASA Field Installations” and adding in their place the words “NASA Field Centers”.

#### § 1212.101 [Amended]

■ 3. Section 1212.101 is amended:

- a. In paragraph (e), by removing the word “Installation,” and adding in its place the word “Center” in two places;
- b. In paragraph (h), by removing the word “related” and adding in its place the word “relates”; and
- c. By removing paragraph (i).

#### Subpart 1212.2—Requests for Access to Records

■ 4. The heading for subpart 1212.2 is revised to read as set forth above.

■ 5. Section 1212.200 is amended by:

- a. Revising the section heading;
- b. Revising the introductory text;
- c. Adding “under 5 U.S.C. 552a(d)(1)” after the word “record” in paragraph (b); and
- d. Adding “under 5 U.S.C. 552a(c)(3)” after the word “records” in paragraph (c).

The revisions read as follows:

#### § 1212.200 Procedures for requesting records subject to the Privacy Act.

The procedures outlined in this subpart 1212.2 apply to the following types of requests made by individuals under the Privacy Act concerning records about themselves:

\* \* \* \* \*

■ 6. Section 1212.201 is amended:

- a. By revising the section heading;
- b. In paragraph (c)(1), by adding “Center Privacy Manager at” before “NASA Headquarters,” and removing the words “Installation Information”;
- c. In paragraph (c)(2)(iv), by adding “time periods in which the records are believed to have been compiled,” before “etc.”; and

■ d. By revising paragraph (e).

The revisions read as follows:

#### § 1212.201 Determining existence of records subject to the Privacy Act.

\* \* \* \* \*

(e) If the Center Privacy Manager receives a request for access, the Privacy Manager will record the date of receipt and immediately forward the request to the responsible system manager for handling.

\* \* \* \* \*

#### § 1212.203 [Amended]

■ 7. In § 1212.203, in paragraph (a), remove the parenthetical statement “(See NASA Management Instruction (NMI) 1382.18)” and in paragraph (b)(2) remove the reference “(g)” and add “(f)” in its place.

#### § 1212.300 [Amended]

■ 8. In § 1212.300 introductory text, after “system of records” in the first sentence, add the words “under the provisions of 5 U.S.C. 552a(d)(2)”.

■ 9. Amend § 1212.400:

- a. In paragraph (a) introductory text, by removing the words “to the Assistant Deputy Administrator”;
- b. By redesignating paragraphs (b) through (e) as (c) through (f), respectively;
- c. By adding new paragraph (b);
- d. In newly redesignated paragraph (c)(1), by removing “Assistant” and adding in its place “Associate,” and adding after “20546” the phrase “or to the Inspector General, NASA Headquarters, Washington, DC 20546, for records as specified in paragraph (b) of this section”; and
- e. In newly redesignated paragraph (e):

■ i. Remove the two occurrences of “Assistant” and add in their place “Associate”

■ ii. Add the words, “or Inspector General for appeals concerning records originating in the Office of the Inspector General” after the first occurrence of “Deputy Administrator”; and

■ iii. Add the words, “or Inspector General” after the second occurrence of “Deputy Administrator”.

The addition reads as follows:

#### § 1212.400 Appeals.

\* \* \* \* \*

(b) The Associate Deputy Administrator or designee is responsible for making final determinations of appeals as specified in paragraphs (a)(1) through (3) of this section for all Agency records, with the exception of those records originating in the Office of the Inspector General for which the

Inspector General is responsible for making final determinations of appeals.

\* \* \* \* \*

#### § 1212.500 [Amended]

■ 10. In § 1212.500, in paragraph (b), remove “Assistant” and add in its place “Associate”.

#### § 1212.501 [Amended]

■ 11. Amend § 1212.501:

- a. In paragraph (a)(1)(i), in the first sentence, by adding the word “sections” before the colon and after the words “except the following”;
- b. In the first sentence of paragraph (a)(1)(ii), by removing the words “there may exist” and adding the words “may exist” following the words “investigative files”; and
- c. In paragraph (a)(2)(ii)(D), by removing “fullfill” and adding in its place “fulfill”.

#### § 1212.601 [Amended]

■ 12. In § 1212.601, in paragraph (b), remove the phrase “, and the NASA system notice shall include a reference to the system notice of the other agency”.

■ 13. In § 1212.603, add a second sentence to read as follows:

#### § 1212.603 Mailing lists.

\* \* \* \* \* This is not to be construed to require the withholding of names and addresses otherwise permitted to be made public.

■ 14. In § 1212.605, in paragraph (a), remove the word “Installation” and add in its place “Center” and after “Security Officer” add “or Center Information Technology Security Officer for electronic records maintained in automated systems” and add a second sentence to read as follows:

#### § 1212.605 Safeguarding information in systems of records.

(a) \* \* \* Safeguards must insure the security and confidentiality of records and protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained.

\* \* \* \* \*

■ 15. In § 1212.701:

- a. Revise the section heading;
- b. In the introductory text, remove “Assistant” and add “Associate” in its place;
- c. Add to the end of paragraph (a) the phrase “, except on those related to records originating in the Office of the Inspector General”; and

■ d. Add to the end of paragraph (c) the phrase “, except for an appeal related to records originating in the Office of the Inspector General”.

The revision reads as follows:

**§ 1212.701 Associate Deputy Administrator.**

\* \* \* \* \*

**§§ 1212.702 through 1212.706 [Redesignated as §§ 1212.703 through 1212.707]**

■ 16. Redesignate §§ 1212.702 through 1212.706 as §§ 1212.703 through 1212.707 and add a new § 1212.702 to read as follows:

**§ 1212.702 The Inspector General.**

The Inspector General is responsible for:

- (a) Making final Agency determinations on appeals related to records originating with the Office of the Inspector General (§ 1212.400), and
- (b) Authorizing an extension for making a final determination on an appeal related to records originating with the Office of the Inspector General (§ 1212.400(e)).

■ 17. In newly redesignated § 1212.703:

- a. Revise the section heading;
- b. In paragraph (a) introductory text, remove the phrase “Associate Administrator for Management Systems and Facilities” and add in its place “NASA Chief Information Officer”;
- c. In paragraph (b):

  - i. Remove the phrase “Associate Administrator for Management Systems and Facilities” and add in its place “Chief Information Officer”;
  - ii. Remove the words “Privacy Officer” and add in its place “NASA Privacy Act Officer”; and
  - iii. Remove the word “or” and the phrase “reporting directly to the Associate Administrator for Management Systems and Facilities”.

The revision reads as follows:

**§ 1212.703 NASA Chief Information Officer.**

\* \* \* \* \*

■ 18. In newly redesignated § 1212.704:

- a. Revise the section heading;
- b. In paragraph (a) introductory text, remove the word “Installations” and add in its place “Centers”;
- c. In paragraph (a)(3), remove the reference “§ 1212.203(g)” and add in its place “§ 1212.203(f)”;
- d. In paragraph (a)(4), remove the reference “§ 1212.704” and add in its place “§ 1212.705”;

- e. Add paragraph (a)(5); and
- f. Remove and reserve paragraph (b).  
The revision reads as follows:

**§ 1212.704 Headquarters and Field Centers or Component Facilities.**

(a) \* \* \*

(5) Establish a position of Center Privacy Manager to assist in carrying out the responsibilities listed in this section.

\* \* \* \* \*

■ 19. In newly redesignated § 1212.705:

- a. Revise paragraph (a)(1);
- b. In paragraph (a)(3), remove the word “Assistant” and add in its place “Associate”;
- c. In paragraph (a)(7), remove the reference “§ 1212.203(g)(1) through (12)” and add in its place “§ 1212.203(f)(1) through (12)”;
- d. In paragraph (a)(12), remove “14 CFR” and add in its place “§” and add the words “of this part” after “1212.203”;
- e. In paragraph (c), remove the word “Installation” and add in its place “Center” and remove the reference “§ 1212.703(a)(4) and (b)” and add in its place “§ 1212.704(a)(4) and (5)”

**§ 1212.705 System manager.**

(a) \* \* \*

(1) Overall compliance with this part, NASA Policy Directive (NPD) 1382.17 and NASA Procedural Requirements (NPR) 1382.1.

\* \* \* \* \*

**Charles F. Bolden, Jr.,**  
*Administrator.*

[FR Doc. 2012-23645 Filed 10-3-12; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510, 520, and 558**

[Docket No. FDA-2012-N-0002]

**New Animal Drugs; Change of Sponsor’s Address; Monensin; Spinosad; Tilmicosin**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect

approval actions for new animal drug applications (NADAs) during August 2012 and to reflect a change of sponsor’s address for Baxter Healthcare Corp. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

**DATES:** This rule is effective October 4, 2012.

**FOR FURTHER INFORMATION CONTACT:**

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

FDA is amending the animal drug regulations to reflect original and supplemental approval actions during August 2012, as listed in table 1 of this document. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room. FOI Summaries may be found listed by application number at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm>. Environmental assessments and findings of no significant impact may be found listed by the established name of the active pharmaceutical ingredient at: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm>.

Also, Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974, has informed FDA of a change of address to One Baxter Pkwy., Deerfield, IL 60015. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect this change.