

**PART 417—LAUNCH SAFETY**

■ 3. The authority citation for part 417 continues to read as follows:

**Authority:** 49 U.S.C. 70101–70121.

■ 4. Amend part 417 by adding the heading of Appendix F in alphabetical order as follows:

**Appendix F of Part 417—[Reserved]**

Issued in Washington, DC, on September 11, 2006.

**Ida M. Klepper,**

*Acting Director, Office of Rulemaking.*

[FR Doc. 06–8235 Filed 9–25–06; 8:45 am]

**BILLING CODE 4910–13–P**

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION****14 CFR Part 1214**

**RIN 2700–AC40**

[Notice: (06–067)]

**Code of Conduct for International Space Station Crew**

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

**ACTION:** Final rule.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) has adopted as final, without change, an interim final rule regarding the policy and procedures for International Space Station crewmembers provided by NASA for flight to the International Space Station.

**DATES:** *Effective Date:* September 26, 2006.

**FOR FURTHER INFORMATION CONTACT:** Mick Schlabs, Senior Attorney, International Law Practice Group, Office of the General Counsel, NASA Headquarters, telephone (202) 358–2068, fax (202) 358–4117.

**SUPPLEMENTARY INFORMATION:****A. Background**

NASA published an interim final rule at 65 FR 80303 on December 21, 2000 to set forth policy and procedures with respect to International Space Station crewmembers provided by NASA for flight to the International Space Station. They apply to all persons so provided, including U.S. Government employees, uniformed members of the Armed Services, citizens who are not employees of the U.S. Government, and foreign nationals.

NASA received no comments on the interim final rule. Therefore, NASA has adopted the interim final rule as a final rule without change.

This rule is not a major Federal action as defined in Executive Order 12866.

**B. Regulatory Flexibility Act**

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., because the administrative notification requirements of the rule are expected to affect less than 10 contracts per year.

**C. Paperwork Reduction Act**

The information collection requirements of the rule do not reach the threshold for requiring the Office of Management and Budget's approval under 44 U.S.C. 3501, et seq.

**List of Subjects in 14 CFR Part 1214**

Code of Conduct for International Space Station Crew.

**Michael D. Griffin,**

*Administrator.*

- Interim Final Rule Adopted as Final without Change.
- Accordingly, the interim final rule implementing certain provisions of the International Space Station (ISS) Intergovernmental Agreement (IGA) regarding ISS crewmembers' observance of an ISS Code of Conduct, which was published at 65 FR 80303 on December 21, 2000, is adopted as a final rule without change.

[FR Doc. 06–8186 Filed 9–25–06; 8:45 am]

**BILLING CODE 7510–13–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 1 and 11**

[Docket No. 2005D–0356]

**Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 4); Availability**

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

**ACTION:** Notice of availability of guidance.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4).” The guidance responds to various questions raised about the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism

Act) and the agency's implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons covered by the regulation who employ 500 or more full-time equivalent employees (FTEs) had to be in compliance by December 9, 2005, and those who employ 11 to 499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006, to be in compliance. “Person” includes an individual, partnership, corporation, and association.

**DATES:** Submit written or electronic comments on the agency guidance at any time.

**ADDRESSES:** You may submit comments, identified by 2005D–0356, by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

**Written Submissions**

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

**Instructions:** All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the “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.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), 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:** Center for Food Safety and Applied Nutrition at 1-888-SAFEFOOD, Fax: 1-877-366-3322, or by e-mail: [industry@fda.gov](mailto:industry@fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the *Federal Register* of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act. The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation who employ 500 or more FTEs had to be in compliance by December 9, 2005, and those who employ 11-499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006 to be in compliance. "Person" includes an individual, partnership, corporation, and association.

On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records." On November 22, 2005, FDA issued a second edition of that guidance and on June 6, 2006, FDA issued a third edition of that guidance. This document is the fourth edition of that guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)" and responds to questions regarding persons covered by the regulation, and persons excluded by the regulation, including additional guidance on the farm exclusion. In addition, we are amending the response to question 4.2 to clarify that while post-harvesting activities related to hay are subject to the rule, certain activities that are part of harvesting remain within the farm exemption. This guidance is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a Level 1 guidance. The

guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Consistent with FDA's good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, persons who employ 500 or more FTEs had to begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, and those who employ 11-499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006, to be in compliance. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and complete the rule's implementation.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of this guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments or two paper copies of any 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 and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/~dms/recguid3.html>.

Dated: September 20, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06-8241 Filed 9-21-06; 1:22 pm]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Lasalocid**

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Purina Mills, Inc. The supplemental NADA provides for the use of a lasalocid Type A medicated article containing 20 percent lasalocid activity per pound to make free-choice Type C medicated feed mineral blocks used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

**DATES:** This rule is effective September 26, 2006.

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: [eric.dubbin@fda.hhs.gov](mailto:eric.dubbin@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812, filed a supplement to NADA 141-171 for use of BOVATEC 91 (lasalocid) Type A medicated article to make Purina Sugar Mag Block 1440 BVT Medicated Mineral Block, a free-choice Type C medicated feed used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The supplement provides for the use of a lasalocid Type A medicated article containing 20 percent lasalocid activity per pound. The supplemental NADA is approved as of August 18, 2006, and the regulations are amended in § 558.311 (21 CFR 558.311) to reflect the approval.