

Actions	Compliance	Procedures
<p>(1) Remove each wing attach barrel nut, bolt, and retainer and do a visual inspection for cracks, corrosion, and fractures.</p> <p>(2) If any signs of cracks, corrosion, or fractures are found on any wing attach barrel nut during the inspection required in paragraph (e)(1) of this AD, replace that wing attach barrel nut, bolt, and retainer with new parts and install to the correct torque value.</p> <p>(3) If no signs of cracks, corrosion, or fractures are found during the inspection required in paragraph (e)(1) of this AD, you may reuse the wing attach barrel nuts and bolts if they have been inspected and are free of deformation and irregularities in the threads and meet the minimum breakaway torque requirement. Reinstall inspected parts to the correct torque value. If the wing attach barrel nuts and bolts are not free of deformation and irregularities in the threads or do not meet the minimum breakaway torque requirement, install new parts to the correct torque value.</p>	<p>Within the next 200 hours time-in-service or 12 months after August 11, 2006 (the effective detailed date of this AD), whichever occurs first, unless already done.</p> <p>Before further flight after the inspection required in paragraph (e)(1) of this AD, unless already done.</p> <p>Before further flight after the inspection required in paragraph (e)(1) of this AD, unless already done.</p>	<p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable.</p> <p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable, and the appropriate maintenance manual.</p> <p>Follow Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, as applicable, and the appropriate maintenance manual.</p>

#### Alternative Methods of Compliance (AMOCs)

(f) The Manager, Fort Worth Airplane Certification Office, FAA, ATTN: Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o MIDO-43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308-3365; facsimile: (210) 308-3370, has the authority to approve alternative methods of compliance for this AD, if requested using the procedures found in 14 CFR 39.19.

#### Related Information

(g) Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, dated March 10, 2006, pertain to the subject of this AD.

#### Material Incorporated by Reference

(h) You must do the actions required by this AD following Mitsubishi Heavy Industries, Ltd. MU-2 Service Bulletins referenced as JCAB T.C.: No. 241, dated July 14, 2004, and FAA T.C.: No. 103/57-004A, pages 1 and 4 dated March 10, 2006, pages 2, 3, 5, 6, and 7 dated August 2, 2004. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get a copy of this service information, contact Mitsubishi Heavy Industries America, Inc., 4951 Airport Parkway, Suite 800, Addison, Texas 75001; telephone: (972) 934-5480; fax: (972) 934-5488, or Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248-3108; facsimile: (972) 248-3321. To review copies of this service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html) or call (202) 741-6030. To

view the AD docket, go to the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001 or on the Internet at <http://dms.dot.gov>. The docket number is FAA-2006-23578; Directorate Identifier 2006-CE-01-AD.

Issued in Kansas City, Missouri, on June 19, 2006.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

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## 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 3); 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 3)." The guidance responds to various questions raised about section 306 of 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 11-499 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 Docket No. 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/docket/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. This document is the third edition of that guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 3)" and responds to questions regarding persons covered by the regulation; persons excluded by the regulation, including additional guidance on the farm and restaurant exclusions; and what information is required in the records established and maintained by warehouse distribution facilities. It 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/guidance.html> or <http://www.cfsan.fda.gov/~dms/recguid3.html>

Dated: June 22, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF THE TREASURY**

### **Internal Revenue Service**

#### **26 CFR Part 1**

**[TD 9262]**

**RIN 1545-BF57**

#### **Computer Software Under Section 199(c)(5)(B); Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to temporary regulations.

**SUMMARY:** This document contains a correction to temporary regulations (TD 9262) that were published in the **Federal Register** on Thursday, June 1, 2006 (71 FR 31074) concerning the application of section 199 of the Internal Revenue Code, which provides a deduction for income attributable to domestic production activities, to certain transactions involving computer software.

**DATES:** These corrections are effective June 1, 2006.