

Title 49 of the United States Code, Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103, "Sovereignty and use of airspace." Under that section, the FAA is charged with developing plans and policy for the use of the navigable airspace and assigning by regulation or order the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. The FAA may modify or revoke an assignment when required in the public interest. This regulation is within the scope of that authority because it is in the public interest to provide greater control of the airspace for the safety of aircraft operating in the vicinity of the newly established airport traffic control tower.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

#### PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

##### § 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 16, 2005, is amended as follows:

*Paragraph 5000 Class D airspace areas extending upward from the surface of the earth.*

\* \* \* \* \*

##### ASW AR D Rogers, AR [New]

Rogers Municipal/Carter Field, Rogers, AR  
Lat. 36°22'20" N, long. 94°06'25" W  
Razorback VOR

Lat. 36°14'47" N, long. 94°07'17" W

That airspace extending upward from the surface up to but not including 3,900 feet

MSL within a 4-mile radius of Rogers Municipal/Carter Field and within 2.2 miles each side of the 005° radial of the Razorback VOR extending from the 4-mile radius to 6.0 miles south of the airport excluding that airspace west of a line (lat. 36°24'10" N., long. 94°10'49" W and lat. 36°16'24" N., long. 94°7'55" W) and excluding the Class C airspace associated with the Northwest Arkansas Regional Airport (XNA). This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

*Paragraph 6000 Class E airspace areas extending upward from the surface of the earth.*

\* \* \* \* \*

##### ASW AR E2 Rogers, AR [Revised]

Rogers Municipal/Carter Field, Rogers, AR  
Lat. 36°22'20" N, long. 94°06'25" W  
Razorback VOR

Lat. 36°14'47" N, long. 94°07'17" W

Within a 4-mile radius of Rogers Municipal/Carter Field and within 2.2 miles each side of the 005° radial of the Razorback VOR extending from the 4-mile radius to 6.0 miles south of the airport excluding that airspace west of a line (lat. 36°24'10" N., long. 94°10'49" W and lat. 36°16'24" N., long. 94°7'55" W) and excluding the Class C airspace associated with the Northwest Arkansas Regional Airport (XNA). This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

\* \* \* \* \*

Issued in Fort Worth, TX, on November 15, 2005.

**William C. Yuknewicz,**

*Acting Area Director, Central En Route and Oceanic Operations.*

[FR Doc. 05–23021 Filed 11–21–05; 8:45 am]

**BILLING CODE 4910–13–M**

## 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 2); 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 2).” 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 must be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

**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 detailed instructions on submitting comments

and additional information on the rulemaking process, 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:** Denise Beavers, Office of Regulations and Policy (HFS-24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1721.

**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 are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records." This guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2)" responds to questions about the final rule on records. 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, the final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. 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>.

Dated: November 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**32 CFR Part 310**

**Department of Defense Privacy Program**

**AGENCY:** Department of Defense.

**ACTION:** Final rule.

**SUMMARY:** The Department of Defense updates policies and responsibilities for the Defense Privacy Program which implements the Privacy Act of 1974 by showing organizational changes and realignments and by revising referenced statutory and regulatory authority.

**DATES:** *Effective Date:* November 7, 2005.

**FOR FURTHER INFORMATION CONTACT:** Mr. Vahan Moushegian, Jr., at (703) 607-2943.

**SUPPLEMENTARY INFORMATION:** The proposed rule was published September 7, 2005 at 70 FR 53135. No comments were received. The Office of the Secretary is therefore adopting the rule as published.

**Executive Order 12866, "Regulatory Planning and Review"**

It has been determined that Privacy Act rules for the Department of Defense are not significant rules. The rules do not (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

**Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. Chapter 6)**

It has been determined that Privacy Act rules for the Department of Defense do not have significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the Department of Defense.