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Issued in Seattle, Washington, on November 4, 2005.

**Raul C. Treviño,**

*Area Director, Western En Route and Oceanic Operations.*

[FR Doc. 05-23017 Filed 11-21-05; 8:45am]

**BILLING CODE 4910-13-M**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2005-22998; Airspace Docket No. 2005-ASW-19]

**Establishment to Class E Airspace; Hillsboro, TX**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** This action establishes the Class E airspace area at Hillsboro Municipal Airport, Hillsboro, TX (INJ), to provide adequate controlled airspace for the area navigation (RNAV) global positioning system (GPS) standard instrument approach procedure (SIAP).  
**DATES:** Effective 0901 UTC, February 16, 2006.

Comments for inclusion in the Rules Docket must be received on or before January 16, 2006.

**ADDRESSES:** Send comments on the rule to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket number, FAA-2005-22998/Airspace Docket No. 2005-ASW-20, at the beginning of your comments. You may also submit comments on the Internet at <http://dms.dot.gov>. Anyone can find and read the comments received in this docket, including the name, address and any other personal information placed in the docket by a commenter. You may review the public docket containing any comments received and this direct final rule in person at the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527) is located on the plaza level of the Department of Transportation NASSIF Building at the street address stated previously.

An informal docket may also be examined during normal business hours at the office of the Air Traffic Division, Airspace Branch, Federal Aviation

Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX. Call the manager, Airspace Branch, ASW-520, telephone (817) 222-5520; fax (817) 222-5981, to make arrangements for your visit.

**FOR FURTHER INFORMATION CONTACT:**

Joseph R. Yadouga, Air Traffic Division, Airspace Branch, Federal Aviation Administration, Southwest Region, Fort Worth, TX 76193-0520; telephone (817) 222-5597.

**SUPPLEMENTARY INFORMATION:** This amendment to 14 CFR part 71 establishes a Class D airspace designation for an airspace area from the surface up to but not including, 3,900 feet MSL at Rogers Municipal/Carter Field, Rogers, AR, and will be published in paragraph 5000 of FAA Order 7400.9N, dated September 1, 2004, and effective September 16, 2005, which is incorporated by reference in 14 CFR 71.1.

This amendment to 14 CFR part 71 also modifies the Class E airspace area extending upward from the surface at Rogers Municipal/Carter Field, Rogers, AR, and will be published in paragraph 6000 of FAA Order 7400.9N, dated September 1, 2005, and effective September 16, 2005, which is incorporated by reference in 14 CFR 71.1.

**The Direct Final Rule Procedure**

The FAA anticipates that this regulation will not result in an adverse or negative comment, and, therefore, issues it as a direct final rule. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

**Comments Invited**

Although this action is in the form of a direct final rule, and was not preceded by a notice of proposed rulemaking, interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications must identify both docket numbers. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

**Agency Findings**

This rule does not have federalism implications, as defined in Executive Order No. 13132, because it does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this rule.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as these routine matters will only affect air traffic procedures and air navigation. I certify that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Authority for This Rulemaking**

The FAA authority to issue rules regarding aviation safety is found in

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.*

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##### 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.

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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]

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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 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