

request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

### The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR part 71), which would revise the Class E airspace at the Gulkana Airport, in Gulkana, AK. The intended effect of this proposal is to revise Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Gulkana Airport, Gulkana, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has amended two SIAPs for the Gulkana Airport. The amended SIAPs are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 15, Amendment (Amdt) 2 and (2) the RNAV (GPS) RWY 33, Amdt 2. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Gulkana Airport area would be revised by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Gulkana Airport, Gulkana, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore —(1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant

rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, 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 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Gulkana Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 14 CFR 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 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

\* \* \* \* \*

*Paragraph 6005 Class E Airspace Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

#### AAL AK E5 Gulkana, AK [Revised]

Gulkana, Gulkana Airport, AK  
(Lat. 62°09'18" N., long. 145°27'16" W.)  
Gulkana VOR/DME, AK  
(Lat. 62°09'14" N., long. 145°26'50" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Gulkana Airport, AK, and within 4 miles east and 4 miles west of the 178°(T)/201°(M) radial of the Gulkana VOR/DME, AK, extending from the 6.5-mile radius to 12.5 miles south of the Gulkana Airport, AK, and within 4 miles either side of the 351°(T)/014°(M) radial of the Gulkana VOR/DME, AK, extending from the 6.5-mile radius to 12.5 miles north of the Gulkana Airport, AK; and that airspace extending upward from 1,200 ft. above the surface within a 67-mile radius of the Gulkana Airport, AK.

\* \* \* \* \*

Issued in Anchorage, AK, on May 16, 2008.

**Anthony M. Wylie,**

*Manager, Alaska Flight Services Information Area Group.*

[FR Doc. E8-11976 Filed 5-28-08; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2008-0457; Airspace Docket No. 08-AAL-16]

#### Proposed Revision of Class E Airspace; Red Dog, AK

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This action proposes to revise Class E airspace at Red Dog, AK. A Special Standard Instrument Approach Procedure (SIAP) and a Special textual Obstacle Departure Procedure (ODP) are being developed for the Red Dog Airport at Red Dog, AK. Additionally, a Special SIAP is being amended. Adoption of this proposal would result in revision of existing Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the Red Dog Airport, Red Dog, AK.

**DATES:** Comments must be received on or before July 14, 2008.

**ADDRESSES:** Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001. You must identify the

docket number FAA-2008-0457/ Airspace Docket No. 08-AAL-16, at the beginning of your comments. You may also submit comments on the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in 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 on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513-7587.

**FOR FURTHER INFORMATION CONTACT:** Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513-7587; telephone number (907) 271-5898; fax: (907) 271-2850; e-mail: [gary.ctr.rolf@faa.gov](mailto:gary.ctr.rolf@faa.gov). Internet address: <http://www.alaska.faa.gov/at>.

#### **SUPPLEMENTARY INFORMATION:**

##### **Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2008-0457/Airspace Docket No. 08-AAL-16." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the

closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

##### **Availability of Notice of Proposed Rulemakings (NPRMs)**

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Documents' Web page at <http://www.access.gpo.gov/nara/index.html>.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

##### **The Proposal**

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR Part 71), which would revise the Class E airspace at the Red Dog Airport, in Red Dog, AK. The intended effect of this proposal is to revise Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Red Dog Airport, Red Dog, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has developed one Special SIAP and one Special textual ODP for the Red Dog Airport. Additionally, one Special SIAP is being amended. The new SIAP is the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 03, Special, Original (Orig). The new SIAP is the Nondirectional Beacon (NDB)/Distance Measuring Equipment (DME) RWY 03, Special, Amendment (Amdt) 1. These procedures are funded privately and are not published in the U.S. Terminal Procedures Alaska publication. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Red Dog Airport area would be revised by this action. The proposed airspace is sufficient in size to contain aircraft

executing the instrument procedures at the Red Dog Airport, Red Dog, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

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

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## The Proposed Amendment

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\* \* \* \* \*

*Paragraph 6005 Class E Airspace Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

#### **AAL AK E5 Red Dog, AK [Revised]**

Red Dog Airport, AK  
(Lat. 68°01'56" N., long. 162°54'14" W.)

That airspace extending upward from 700 feet above the surface within an 11-mile radius of the Red Dog Airport, AK, and 4 miles either side of the 219°(T)/238°(M) bearing from the Red Dog Airport, AK, extending from the 11-mile radius to 14.5 miles southwest of the Red Dog Airport, AK; and that airspace extending upward from 1,200 ft. above the surface within a 72.5-mile radius of the Red Dog Airport, AK.

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Issued in Anchorage, AK, on May 16, 2008.

**Anthony M. Wylie,**

*Manager, Alaska Flight Services Information Area Group.*

[FR Doc. E8–11971 Filed 5–28–08; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 201**

[Docket No. FDA–2006–N–0515] (Formerly Docket No. 2006N–0467)

RIN 0910–AF11

### **Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations concerning the format and content of the “Pregnancy”, “Labor and delivery”, and “Nursing mothers” subsections of the “Use in Specific Populations” section of the labeling for human prescription drug and biological products. The agency is proposing to require that labeling include a summary of the risks of using a drug during pregnancy and lactation and a discussion of the data supporting that summary. The labeling would also include relevant clinical information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and/or lactation. The proposal would eliminate the current pregnancy categories A, B, C, D, and X. The “Labor and delivery” subsection would be eliminated because information on labor and delivery is included in the proposed “Pregnancy” subsection. The proposed rule is intended to create a consistent format for providing information about the effects of a drug on pregnancy and lactation that will be useful for decisionmaking by women of childbearing age and their health care providers.

**DATES:** Submit written or electronic comments on the proposed rule by August 27, 2008. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by June 30, 2008, (see the “Paperwork Reduction Act of 1995” section of this document).

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2006–N–0515 and/or RIN number 0910–AF11, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory

Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### *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, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*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.regulations.gov>, 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.regulations.gov> 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:**

Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20856, 301–827–6210.

#### **SUPPLEMENTARY INFORMATION:**

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