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/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration (FAA), 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

This action proposes to amend Title 14, Code of Federal Regulations (14 CFR), Part 71 by adding additional Class E airspace extending upward from 700 feet above the surface for SIAPs operations at Moore County Airport, Dumas, TX. Adjustment to the geographic coordinates would be made in accordance with the FAA's National Aeronautical Charting Office. Controlled airspace is needed for the safety and management of IFR operations at the airport.

Class E airspace areas are published in Paragraph 6005 of FAA Order 7400.9T, dated August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation 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 U.S. 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 I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would add additional controlled airspace at Moore County Airport, Dumas, TX.

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, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009, is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW TX E5 Dumas, TX [Amended]

Moore County Airport, TX

(Lat. 35°51′29″ N., long. 102°00′47″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Moore County Airport and within 1.9 miles each side of the 023° bearing from the airport extending from the 6.8-mile radius to 8.9 miles northeast of the airport, and within 4 miles each side of the 203° bearing from the airport extending from the 6.8-mile radius to 11.2 miles southwest of the airport.

* * * * *

Issued in Fort Worth, TX, on December 17, 2009.

Richard Farrell,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. E9–30866 Filed 12–28–09; 8:45 am]

BILLING CODE 4901–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–1009; Airspace Docket No. 09–AWP–11]

Proposed Modification of Class E Airspace; Oxnard, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Point Mugu NAWS, Oxnard, CA. Additional controlled airspace is necessary to accommodate aircraft flying in the Los Angeles Air Route Traffic Control Center's (ARTCC's) airspace area. The FAA is proposing this action to enhance the safety and management of aircraft operations in Los Angeles ARTCC's airspace.

DATES: Comments must be received on or before February 12, 2010.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone (202) 366–9826. You must identify FAA Docket No. FAA–2009–1009; Airspace Docket No. 09–AWP–11, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

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 (FAA Docket No. FAA–2009–1009 and Airspace Docket No. 09–AWP–11) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2009–1009 and Airspace Docket No. 09–AWP–11''. 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 action 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 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/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace at Point Mugu NAWS, Oxnard, CA. Additional controlled airspace is necessary to accommodate the vectoring of aircraft flying en route, in and out of the Los Angeles ARTCC's airspace area. This action would enhance the safety and management of aircraft operations in Los Angeles ARTCC's airspace.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9T, signed August 27, 2009, and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this 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. Therefore, this proposed regulation (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 proposed rule, when promulgated, would 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 U.S. Code. Subtitle 1, section 106, describes the authority for 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. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace.

This regulation is within the scope of that authority as it establishes additional controlled airspace at Point Mugu NAWS, Oxnard, CA.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 the FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Oxnard, CA

Point Mugu NAWS, CA
(Lat. 34°07′13″ N., long. 119°07′15″ W.)

That airspace extending upward from 700 feet above the surface beginning at lat. 34°01′56″ N., long. 119°01′44″ W.; to lat. 34°02′30″ N., long. 118°53′33″ W.; to lat. 34°19′30″ N., long. 118°53′03″ W.; to lat. 34°19′30″ N., long. 119°29′53″ W.; thence 3 miles west of and parallel to the shoreline to lat. 34°14′50″ N., long. 119°22′03″ W.; to lat. 34°14′45″ N., long. 119°23′33″ W.; to lat. 34°06′55″ N., long. 119°22′33″ W.; to lat. 34°07′41″ N., long. 119°15′40″ W., thence via a 7-mile radius of Point Mugu NAWS to the point of beginning. That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 34°30′00″ N., long. 118°50′03″ W.; to lat. 34°00′00″ N., long. 118°50′03″ W.; to lat. 34°00′00″ N., long. 119°05′00″ W.; to lat. 33°52′03″ N., long. 119°06′59″ W.; to lat. 33°28′30″ N., long. 119°07′03″ W.; to lat. 33°28′30″ N., long. 118°47′00″ W.; to lat. 33°19′30″ N., long. 118°37′03″ W.; to lat. 32°53′00″ N., long. 119°13′00″ W.; to lat. 33°05′00″ N., long. 119°45′07″ W.; to lat. 33°53′00″ N., long. 120°38′00″ W.; to lat. 33°54′00″ N., long. 120°00′03″ W.; to lat. 34°20′00″ N., long. 120°00′04″ W.; to lat. 34°20′00″ N., long. 119°30′03″ W.; to lat. 34°30′00″ N., long. 119°30′03″ W., thence to the point of beginning. That airspace extending upward from 5,000 feet MSL bounded by a line beginning at lat. 34°08′00″ N., long. 120°00′03″ W.; to lat. 33°54′00″ N., long. 120°00′03″ W.; to lat. 33°53′00″ N., long. 120°38′00″ W.; to lat. 33°55′00″ N., long. 120°40′00″ W.; to lat. 34°00′00″ N., long. 120°43′00″ W.; to lat. 34°06′15″ N., long.

120°30′04″ W.; to lat. 34°08′00″ N., long. 120°26′04″ W., thence to the point of beginning.

* * * * *

Issued in Seattle, Washington, on December 16, 2009.

William Buck,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. E9–30796 Filed 12–28–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. FDA–2009–N–0592]

RIN No. 0910–AG32

Informed Consent Elements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity for public comment.

SUMMARY: The Food and Drug Administration (FDA or agency) is issuing a proposed rule that, if finalized, would amend the informed consent regulations to require that the informed consent documents and processes for applicable drug, biologic, and device clinical investigations include a statement that clinical trial information for such clinical investigations has been or will be submitted to the National Institutes of Health/National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank. The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that FDA update its informed consent regulations to require that the informed consent documents and processes for certain clinical investigations include a statement that clinical trial information for such investigations has been or will be submitted for inclusion in the clinical trial registry databank.

DATES: Submit written or electronic comments on the proposed rule by March 1, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0592 and/or RIN number 0910–AG32, by any of the following methods.

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.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) 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, 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: Jarilyn Dupont, Office of Policy, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDAAA was enacted on September 27, 2007. Section 801 of FDAAA amends the Public Health Service (PHS) Act to require the Secretary of the Department of Health and Human Services (HHS), acting through the Director of NIH, to expand the clinical trial registry databank established under section 113 of the 1997 Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115, currently codified at 42 U.S.C. 282(i)) and to ensure that the databank is made publicly available through the Internet. Section 801 provides for the expansion of the registry databank through requiring investigators and sponsors to submit certain information about any applicable clinical trial to NIH/NLM for inclusion in the clinical trial registry databank. Section 801's requirements apply to applicable device clinical trials or applicable drug clinical trials, as defined in the statute. Under FDAAA, applicable drug clinical trials include clinical trials for biological products regulated under section 351 of the PHS Act (42 U.S.C. 262). Section 801 also requires the Secretary to ensure that the databank includes links to results information for those clinical investigations that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved.

Section 801(b)(3)(A) of FDAAA also amends section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) to require that the Secretary update FDA's informed consent regulations to require that informed consent documents and processes for the clinical investigations in question include a statement that clinical trial information has been or will be submitted to this registry databank. The current informed consent regulations do not include provisions addressing the clinical trial registry databank. (*See* part 50 (21 CFR part 50); part 312 (21 CFR part 312); and 21 CFR 812.2(b)(1)(iii) and 812.25(g).) Specifically, section 801(b)(3)(A) of FDAAA states:

> NEW DRUGS AND DEVICES.—
>
> (A) INVESTIGATIONAL NEW DRUGS.—
>
> Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

II. Background

FDA has various regulations that govern the conduct of clinical investigations. The informed consent regulations provide protection to subjects in clinical investigations conducted under FDA's jurisdiction. (*See* part 50.) These informed consent regulations are based on ethics codes such as the Nuremberg Code (Ref. 1), the Declaration of Helsinki (Ref. 2), the National Research Act (Ref. 3), and the Belmont Report (Ref. 4); these codes embody the basic ethical principles relevant to the protection of human research subjects. (*See* 60 FR 49086, September 21, 1995, and 44 FR 47713, August 14, 1979, for a detailed discussion of the ethical basis for the agency's regulations governing human subject protection.) These principles identify standards to protect participants from unethical practices, allow subjects to have equal access to, opportunity to participate in, and the ability to withdraw from clinical trials voluntarily, educate participants so they make autonomous decisions, and