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(f), 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 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, 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 Hanford, CA [Amended]

Hanford Municipal Airport, CA
(Lat. 36°19′00″ N, long. 119°37′40″ W)

That airspace extending upward from 700 feet above the surface within 1.8 miles southwest and 3.2 miles northeast of a 332° bearing from Hanford Municipal Airport extending to 6.2 miles northwest of the airport, and within 1.8 miles southwest and 3.2 miles northeast of a 152° bearing from the airport extending to 6.2 miles southeast of the airport, and within 1.3 miles each side of a 067° bearing from the airport extending to 7.7 miles northeast of the airport.

Issued in Seattle, Washington, on February 7, 2018.

B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–03409 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0972; Airspace Docket No. 16–ANM–9]

Establishment of Class E Airspace, Rangely, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface, at Rangely Airport, Rangely, CO, to accommodate new area navigation (RNAV) procedures at the airport. This action ensures the safety and management of instrument flight rules (IFR) operations within the National Airspace System.

DATES: Effective 0901 UTC, May 24, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2253.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's 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. 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 establishes Class E airspace extending upward from 700 feet above the earth at Rangely Airport, Rangely, CO, to support IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (82 FR 57554; December 6, 2017) for Docket No. FAA–2017–0972 to establish Class E airspace extending upward from 700 feet above the surface at Rangely Airport, Rangely, CO. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Rangely Airport, Rangely, CO, within an area approximately 10 miles wide, from north to south, and extending to approximately 10 miles east and 12 miles west of the airport.

Regulatory Notices and Analyses

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, is non-controversial and unlikely to result in adverse or negative comments. 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 only affects 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.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA

Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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(f), 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 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

ANM CO E5 Rangely, CO [New]

Rangely Airport, CO

(Lat. 40°05′38″ N, long. 108°45′47″ W)

That airspace extending upward from 700 feet above the surface of Rangely Airport within the area bounded by lat. 40°04′58″ N, long. 109°01′51″ W; to lat. 40°12′20″ N, long. 108°35′41″ W; to lat. 40°09′07″ N, long. 108°32′59″ W; to lat. 40°01′42″ N, long. 108°36′14″ W; to lat. 39°59′18″ N, long. 108°45′09″ W; to lat. 40°00′25″ N, long. 109°01′00″ W; thence to the point of beginning.

Issued in Seattle, Washington, on February 7, 2018.

B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–03401 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2013–N–0080]

RIN 0910–AG48

Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations on acceptance of data from clinical investigations for medical devices. We are requiring that data submitted from clinical investigations conducted outside the United States intended to support an investigational device exemption (IDE) application, a premarket notification (510(k)) submission, a request for De Novo classification, a premarket approval (PMA) application, a product development protocol (PDP) application, or a humanitarian device exemption (HDE) application be from investigations conducted in accordance with good clinical practice (GCP), which includes obtaining and documenting the review and approval of the clinical investigation by an independent ethics committee (IEC) and obtaining and documenting freely given informed consent of subjects, which includes individuals whose specimens are used in investigations of medical devices. The final rule updates the criteria for FDA acceptance of data from clinical investigations conducted outside the United States to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects. As part of this final rule, we are also amending the IDE, 510(k), and HDE regulations to address the requirements for FDA acceptance of data from clinical investigations conducted inside the United States. The final rule provides consistency in FDA requirements for acceptance of data from clinical investigations, whatever the application or submission type.

DATES: This rule is effective February 21, 2019. See section III of this document for additional explanation of the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT: Soma Kalb, Director, Investigational Device Exemptions Staff, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993, 301–796–6359; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Final Rule

Through this rule, FDA is updating the standards for FDA acceptance of data from clinical investigations conducted outside the United States to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects. In this rule, FDA is amending the regulations for PMA applications, HDE applications, IDE applications, and premarket notification submissions. As part of this rule, FDA also is amending the IDE regulations and the premarket notification regulations to address the requirements for FDA acceptance of data from clinical investigations conducted inside the United States. The amendments are intended to provide consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.

Legal Authority

FDA is issuing this rule under the authority of the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that apply to medical devices (21 U.S.C. 301 *et seq.*), including section 520(g) regarding IDEs (21 U.S.C. 306j(g)), section 515(c)(1)(A) and (d)(2) regarding PMAs (21 U.S.C. 360e(c)(1)(A) and (d)(2)), sections 510(k) and 513(i) regarding premarket notifications and determinations of substantial equivalence (21 U.S.C. 360(k) and 360c(i), respectively), section 520(m) regarding HDEs, section 513(f)(2) regarding De Novo classifications, section 569B regarding acceptance of data from clinical investigations conducted outside the United States (21 U.S.C. 360bbb–8b), and section 701(a) regarding regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)).

Summary of the Major Provisions of the Final Rule

This rule requires that sponsors and applicants of submissions and applications that include clinical investigations conducted outside the United States and submitted to support an IDE or device marketing application or submission provide statements and information regarding how the