(ii) MHI RJ Service Bulletin 670BA–28–041, Revision B, dated January 27, 2021.

(iii) MHI RJ Temporary Revision (TR) 2S4–002, dated September 1, 2021.

(iv) MHI RJ TR 2S4–003, dated September 1, 2021.

(v) [MHI RJ] CRJ Series Regional Jet TR ALI–0740, dated October 13, 2020.

(vi) [MHI RJ] CRJ Series Regional Jet TR ALI–0741, dated October 13, 2020.

(vii) [MHI RJ] CRJ700/900/1000 Series Regional Jet TR ALI–0751, dated April 8, 2021.

(3) For MHI RJ Aviation ULC service information identified in this AD, contact MHI RJ Aviation Group, Customer Response Center, 3655 Ave. des Grandes-Tourelles, Suite 110, Boisbriand, Québec J7H 0E2 Canada; North America toll-free telephone 833–990–7272 or direct-dial telephone 450–990–7272; fax 514–855–8501; email *thd.crj@mhirj.com;* internet *mhirj.com*.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on August 29, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–22333 Filed 10–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0132; Airspace Docket No. 22–ACE–5]

RIN 2120–AA66

Establishment of Class E Airspace; Ellsworth, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Ellsworth, KS. This action is the result of new public instrument procedures being established at Ellsworth Municipal Airport, Ellsworth, KS.

DATES: Effective 0901 UTC, December 29, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://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.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 surface at Ellsworth Municipal Airport, Ellsworth, KS, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 11361; March 1, 2022) for Docket No. FAA–2022–0132 to establish Class E airspace at Ellsworth, KS. 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 JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace extending upward from 700 feet above within a 6.5-mile radius of Ellsworth Municipal Airport, Ellsworth, KS.

This action is necessary to support new public instrument procedures at Ellsworth Municipal Airport.

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

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, does 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 5–6.5.a. 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 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 JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

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

* * * * *

ACE KS E5 Ellsworth, KS [Establish]

Ellsworth Municipal Airport, KS
(Lat. 38°45′02″ N, long. 98°13′49″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Ellsworth Municipal Airport.

Issued in Fort Worth, Texas, on October 7, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–22291 Filed 10–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2015–N–0030]

Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of period before enforcement.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard memorandum of understanding (MOU) with FDA addressing certain distributions of compounded human drug products. FDA is extending the period, which was scheduled to end on October 27, 2022, until the effective date of a final rule regarding certain distributions of compounded human drug products and publication of an updated standard MOU.

DATES: FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard MOU with FDA as of October 21, 2022.

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993–0002, 301–796–9349.

SUPPLEMENTARY INFORMATION: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following sections of the FD&C Act: (1) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) the drug product is compounded in a State that has entered into an MOU with the FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (statutory 5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

In the **Federal Register** of October 27, 2020 (85 FR 68074), FDA announced the availability of a standard MOU describing the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

In the October 27, 2020, **Federal Register** notice, FDA stated that it was providing a 365-day period that was scheduled to end on October 27, 2021, for States to decide whether to sign the standard MOU before FDA intended to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU. Soon after announcing the availability of the standard MOU, FDA was sued by several compounding pharmacies regarding the standard MOU in the U.S. District Court for the District of Columbia (*Wellness Pharmacy, Inc.* v. *Becerra* (D.D.C. Sep. 21, 2021)).

In the **Federal Register** of August 9, 2021 (86 FR 43550), FDA extended the period to October 27, 2022, before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU.

On September 21, 2021, the Court remanded the standard MOU to FDA to either certify that it will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis. To undertake this analysis more fully and ensure a robust framework for these important public health protections, FDA intends to engage in notice-and-comment rulemaking regarding certain distributions of compounded human drug products under section 503A of the FD&C Act. FDA considers the standard MOU published in October 2020 to be suspended. This means that during the rulemaking process, FDA will not enter into new agreements with States based on the October 2020 standard MOU. FDA does not expect States that have signed the October 2020 standard MOU to carry out the activities described in the MOU. The October 2020 standard MOU will be updated based on the content of a final rule, and FDA intends to announce a new opportunity for all