DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–5801; Airspace Docket No. 15–AGL–18]

Establishment of Class E Airspace; Beach, ND

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 Beach Airport, Beach, ND, to accommodate new Standard Instrument Approach Procedures for the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, July 21, 2016. 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 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, 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 FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone: 817–222–5857.

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 at Beach Airport, Beach ND.

History

On February 4, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E airspace extending upward from 700 feet above the surface at Beach Airport, Beach, ND. (81 FR 5948). Docket No. FAA–2015–5801. 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 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations 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 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14, Code of Federal Regulations (14 CFR), Part 71 by establishing Class E airspace extending upward from 700 feet above the surface within an 9-mile radius of Beach Airport, Beach, ND, to accommodate new Standard Instrument Approach Procedures for IFR operations at 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, 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 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

List 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 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

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

* * * * *

AGL ND E5 Beach, ND [New]

Beach Airport, ND

(Lat. 46°55′31″ N., long. 103°58′55″ W.)

That airspace extending upward from 700 feet above the surface within a 9-mile radius of Beach Airport.

Issued in Fort Worth, TX, on April 27, 2016.

Vonnie Royal,

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

[FR Doc. 2016–10736 Filed 5–10–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2012–N–0447]

RIN 0910–AG45

Antimicrobial Animal Drug Sales and Distribution Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to require that the sponsor of each approved or conditionally approved new animal drug product that contains an antimicrobial active ingredient submit an annual report to us on the amount of each such ingredient in the drug product that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. This final rule codifies the reporting requirements established in section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA). The final rule also includes an additional reporting provision intended to enhance our understanding of antimicrobial new animal drug sales intended for use in specific food-producing animal species and the relationship between such sales and antimicrobial resistance.

DATES: This rule is effective July 11, 2016. For the applicable compliance dates, please see section V, ''Effective and Compliance Dates'' in **SUPPLEMENTARY INFORMATION.**

ADDRESSES: 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 final rule 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: *With regard to the final rule:* Neal Bataller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, *Neal.Bataller@fda.hhs.gov.*

With regard to the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The purpose of this rulemaking is to change the way we collect and report information related to the distribution and sale of approved or conditionally approved antimicrobial new animal drug products for use in food-producing animals.

Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b), as amended by section 105 of ADUFA (ADUFA 105) (Title I of Pub. L. 110–316), to submit to us an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. We are also required by ADUFA 105 to publish annual summary reports of the data we receive from animal drug sponsors. In accordance with the law, sponsors of the affected antimicrobial new animal drug products began submitting their sales and distribution data to us on an annual basis, and we have published summaries of such data for each calendar year beginning with 2009. Since that time, we have published two documents inviting public input on potential changes to our regulations relating to records and reports for approved new animal drugs, including an advance notice of proposed rulemaking (77 FR 44177, July 27, 2012) and a proposed rule (80 FR 28863, May 20, 2015). This final rule amends our existing records and reports regulation in part 514 (21 CFR part 514) to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. ADUFA 105 was enacted to assist us in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance. This rule includes an additional reporting provision intended to improve our understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species. This additional provision assists us in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance.

Finalizing this rule will assist us in assessing the rate at which sponsors are voluntarily revising their FDA-approved labeled use conditions to promote the judicious use of medically important antimicrobial drugs in food-producing animals. In December 2013, we published guidance for industry (GFI) #213 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*), a guidance that calls on sponsors of approved medically important antimicrobial new animal drugs administered through medicated feed or water to voluntarily make changes to remove production uses (growth promotion and feed efficiency) from their product labels and bring the remaining therapeutic uses of these products (to treat, control, or prevent disease) under the oversight of a veterinarian by the end of December 2016. All affected drug sponsors committed to implementing the changes described in guidance for industry (GFI) #213 by the December 2016 target date. Once the changes are fully implemented, it will be illegal to use these medically important antibiotics for production purposes, and animal producers will first need to obtain authorization from a licensed veterinarian to use them for therapeutic