

Issued in Jamaica, New York on May 18, 2004.

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[FR Doc. 04-11895 Filed 5-26-04; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2004-17722; Airspace
Docket No. 04-ACE-34]

Modification of Class E Airspace; McCook, NE

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Direct final rule; request for
comments.

SUMMARY: This action amends title 14 Code of Federal Regulations, part 71 (14 CFR 71) by revising Class E airspace areas at McCook, NE. A review of the Class E airspace surface area and the Class E airspace area extending upward from 700 feet above the surface at McCook, NE reveals neither reflects the current McCook Municipal Airport airport reference point (ARP). The Class E airspace surface area does not comply with criteria for extensions and the Class Airspace area extending upward from 700 feet above ground level (AGL) does not comply with criteria for diverse departures. These airspace areas are modified to conform to the criteria in FAA Orders.

DATES: This direct final rule is effective on 0901 UTC, September 30, 2004. Comments for inclusion in the Rules Docket must be received on or before July 26, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket number FAA-2004-17722/ Airspace Docket No. 04-ACE-34, at the beginning of your comments. You may also submit comments on the Internet at <http://dms.dot.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.

FOR FURTHER INFORMATION CONTACT:

Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 modifies the Class E surface area and the Class E airspace area extending upward from 700 feet above the surface at McCook, NE. An examination of controlled airspace for McCook, NE revealed that the McCook Municipal Airport ARP used in the legal descriptions for both Class E airspace areas is incorrect. Extensions to the Class E surface area are redefined relative to the McCook very high frequency omni-directional range (VOR)/distance measuring equipment (DME) facility and its radials. The Class E airspace area extending upward from 700 feet above the surface is increased from a 6.8-mile radius to a 7.6-mile radius of McCook Municipal Airport in order to comply with the criteria for 700 feet AGL airspace required for diverse departures. These modifications bring the legal descriptions of the McCook, NE Class E airspace areas into compliance with FAA Orders 7400.2E, Procedures for Handling Airspace Matters, and 8260.19C, Flight Procedures and Airspace. Class E airspace areas designed as surface areas are published in Paragraph 6002 of FAA Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of the same Order. The Class E airspace designations listed in this document would be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final

rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this 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-2004-17722/Airspace Docket No. 04-ACE-34." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 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 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 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ACE NE E2 McCook, NE

McCook Municipal Airport, NE

(Lat. 40°12'23" N., long. 100°35'32" W.)

McCook VOR/DME

(Lat. 40°12'14" N., long. 100°35'39" W.)

Within a 4.1-mile radius of McCook Municipal Airport and within 1.8 miles each side of the McCook VOR/DME 122° radial extending from the 4.1-mile radius of the airport to 7 miles southeast of the VOR/DME and within 1.8 miles each side of the McCook VOR/DME 326° radial extending from the 4.1-mile radius of the airport to 7 miles northwest of the VOR/DME. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Director.

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

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ACE NE E5 McCook, NE

McCook Municipal Airport, NE

(Lat. 40°12'23" N., long. 100°35'32" W.)

That airspace extending upward from 700 feet above the surface within a 7.6-mile radius of McCook Municipal Airport.

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Issued in Kansas City, MO, on May 11, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–11894 Filed 5–26–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 510 and 558**

[Docket No. 1993P–0174]

Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is changing the regulations for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA is clarifying: What data are required to demonstrate chemical and physical stability of a drug in liquid feed, how such data may be submitted for use in the new animal drug approval process, and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA is ensuring that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996.

DATES: This rule is effective June 28, 2004.

FOR FURTHER INFORMATION CONTACT:

Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: dmomcilo@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of May 28, 2003 (68 FR 31645), FDA proposed changing regulations for liquid medicated feed and free-choice medicated feed and provided 90 days for comments on the proposed changes.

Several events led to the development of the proposed rule. First, an April 30, 1993, citizen petition requested that

FDA amend § 558.5 (21 CFR 558.5) to clarify the information and data needed to demonstrate chemical and positional (physical) stability in liquid medicated feeds and describe circumstances under which a medicated feed application (MFA) will or will not be required. Second, our November 21, 1996 (61 FR 59209) advanced notice of proposed rulemaking, which we issued seeking comments concerning various issues for the development of regulations implementing provisions of ADAA, prompted the Animal Feed Industry Association to propose changes to the new animal drug requirements regarding free choice administration in feeds (§ 510.455 (21 CFR 510.455)). The proposed changes to § 510.455 would adopt the terms of feed mill licensing in accordance with ADAA and allow a feed manufacturer to submit a new animal drug application (NADA) for the approval of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. This document contains the liquid medicated feed and free-choice medicated feed final rules.

II. Summary of the Proposed Rule**A. Liquid Medicated Feed**

The proposed rule had the following objectives: (1) Replaced the references to “medicated feed application” in the current rule with the term “medicated feed mill license,” (2) defined the types of liquid medicated feed covered by this regulation, (3) clarified the types of approvals required for liquid medicated feed, (4) explained that an approval is required for a drug intended for use in a liquid feed and clarifies the procedures and requirements for demonstrating chemical and physical stability of a drug in liquid feed, (5) permitted submission of the stability data through a master file (MF) for reference by a subsequent applicant, (6) explained what information will be included in the published approval of a drug for use in liquid feed, (7) identified the conditions under which an approved medicated feed mill license will be required for the manufacture of a liquid medicated feed, and (8) described the labeling provisions for several drugs approved for use in water but not in liquid feed. We invited comments on whether or not the waiver provision needs to continue to be available because no one has invoked the provision since its inception in 1973.

B. Free-Choice Medicated Feed

The proposed rule had the following objectives: (1) Modified the current rule