

County Municipal Airport revealed it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The criteria in FAA Order 7400.2E for an aircraft to reach 1200 feet AGL, taking into consideration rising terrain, is based on a standard climb gradient of 200 feet per mile plus the distance from the airport reference point to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. Additionally, the examination revealed the dimensions of the extension to the airspace area were not in compliance with FAA Order 8260.19C, Flight Procedures and Airspace. This amendment expands the airspace area from a 6-mile radius to a 7.3-mile radius of Cheyenne County Municipal Airport, decreases the length of the extension of the Class E airspace area from 7.4 to 7 miles from the St. Francis nondirectional radio beacon (NDB), decreases the width of the extension from 2.6 to 1.9 miles each side of the centerline and brings the legal description of the St. Francis, KS Class E airspace area into compliance with FAA Orders 7400.2E and 8260.19C. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, 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.

#### 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-2004-18821/Airspace Docket No. 04-ACE-47." 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 7400.9M, dated August 30, 2004, and effective September 15, 2004, 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 St. Francis, KS

St. Francis, Cheyenne County Municipal Airport, KS  
(Lat. 39°40'40" N., long. 101°47'45" W.)

St. Francis NDB  
(Lat. 39°43'37" N., long. 101°45'54" W.)

That airspace extending upward from 700 feet above the surface within a 7.3-mile radius of Cheyenne County Municipal Airport and within 1.9 miles each side of the 144° bearing from the St. Francis NDB extending from the 7.3-mile radius of the airport to 7 miles southeast of the NDB.

\* \* \* \* \*

Issued in Kansas City, MO, on September 16, 2004.

**Paul J. Sheridan,**

*Manager, Air Traffic Division, Central Region.*  
[FR Doc. 04-21528 Filed 9-23-04; 8:45 am]

**BILLING CODE 4910-13-M**

#### DEPARTMENT OF TRANSPORTATION

#### Federal Aviation Administration

#### 14 CFR Part 71

**[Docket No. FAA-2004-18823; Airspace Docket No. 04-ACE-49]**

#### Modification Class E Airspace; Burwell, 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 at Burwell, NE. A review of controlled airspace for Cram Field revealed it does not comply with the criteria for 700 feet above ground level (AGL) airspace required for diverse departures. The area is modified and enlarged to conform to the criteria in FAA Orders.

**DATES:** This direct final rule is effective on 0901 UTC, January 20, 2005. Comments for inclusion in the Rules Docket must be received on or before November 1, 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-2004-18823/Airspace Docket No. 04-ACE-49, 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: (819) 329-2524.

**SUPPLEMENTARY INFORMATION:** This amendment to 14 CFR 71 modifies the Class E airspace area extending upward from 700 feet above the surface at Burwell, NE. An examination of controlled airspace for Cram Field revealed it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The criteria in FAA Order 7400.2E for an aircraft to reach 1200 feet AGL, taking into consideration rising terrain, is based on a standard climb gradient of 200 feet per mile plus the distance from the airport reference point (ARP) to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. This amendment expands the airspace area from a 6-mile radius to an 8.3-mile radius of Cram Field, eliminates the extension to the airspace area, deletes reference to the Burwell nondirectional radio beacon (NDB) in the legal description and brings the legal description of the Burwell, NE Class E airspace area into compliance with FAA

Order 7400.2E. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, 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.

#### **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-2004-18823/Airspace Docket No. 04-ACE-49." 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 7400.9M, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

\* \* \* \* \*

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

\* \* \* \* \*

#### **ACE NE E5 Burwell, NE**

Burwell, Cram Field, NE

(Lat. 41°46'36" N., long. 99°08'59" W.)

That airspace extending upward from 700 feet above the surface within an 8.3-mile radius of Cram Field.

\* \* \* \* \*

Issued in Kansas City, MO, on September 16, 2004.

**Paul J. Sheridan,**

*Manager, Air Traffic Division, Central Region.*  
[FR Doc. 04-21530 Filed 9-23-04; 8:45 am]

**BILLING CODE 4910-13-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

##### Oral Dosage Form New Animal Drugs; Ivermectin Liquid

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides revised labeling, including the addition of four new species of internal parasites, for ivermectin oral liquid used in horses.

**DATES:** This rule is effective September 24, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Martine Hartogensis, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7815, e-mail:

*martine.hartogensis@fda.gov.*

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 140-439 for EQVALAN (ivermectin) Oral Liquid for Horses. The supplemental application provides for revisions to the labeled indications. Specifically, the supplement provides for the use of ivermectin oral liquid for the treatment and control of *Craterostomum acuticaudatum*, *Petrovinema poculum*, and *Coronocyclus* spp., including *Coronocyclus coronatus* and *Coronocyclus labratus*. The label descriptions of some currently approved parasite genera are also being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature. In addition, under the sub-heading "Small Strongyles," the labeling has been revised to separate the

listing of adult species from the fourth-stage larvae. The supplemental NADA is approved as of August 9, 2004, and 21 CFR 520.1195 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 9, 2004. This marketing exclusivity only applies to the parasites for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Section 520.1195 is amended by revising paragraphs (b), (e)(1)(ii), and (e)(1)(iii) to read as follows:

#### § 520.1195 Ivermectin liquid.

\* \* \* \* \*

(b) **Sponsors.** See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1)(i),

(e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) Nos. 051259, 058829, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(ii) *Indications for use.* For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicaudatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults), *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp. (B) Large Strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. edentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); Small Strongyles including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); Ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); Hairworms (*Trichostrongylus*