

public interest require adoption of the rule. The FAA has determined that this correction will not change the meaning of the action nor add any additional burden on the public beyond that already published. This action corrects the state identification and confirms the effective date of the direct final rule.

The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on December 3, 1998. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Correction

In rule FR Doc. 98-21475 published in the **Federal Register** on August 11, 1998, 63 FR 42692, make the following correction to the Denison Municipal Airport, state identification incorporated by reference in 14 CFR 71.1:

\$ 71.1 [Corrected]

ACE IA E5 Denison, IA [Corrected]

On page 42693, in the third column, under ACE IA Denison, IA [Revised] change "Denison Municipal Airport, KS" to read "Denison Municipal Airport, IA."

Issued in Kansas City, MO on September 22, 1998.

Donald F. Hensley,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98-27256 Filed 10-8-98; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98-ACE-27]

Amendment to Class E Airspace; Ottumwa, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Ottumwa, IA. **DATES:** The direct final rule published at 63 FR 44127 is effective on 0901 UTC, December 3, 1998.

FOR FURTHER INFORMATION CONTACT:

Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri, 64106; telephone: (816) 426-3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on August 18, 1998 (63 FR 44127). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on December 3, 1998. NO adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on September 22, 1998.

Donald F. Hensley,

Acting Manager, Air Traffic Division, Central Region.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98-ACE-26]

Amendment to Class E Airspace; Clinton, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Clinton, IA.

DATES: The direct final rule published at 63 FR 44378 is effective on 0901 UTC, December 3, 1998.

FOR FURTHER INFORMATION CONTACT:

Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri, 64106; telephone: (816) 426-3408.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on August 19, 1998 (63 FR 44378). The FAA uses the direct final rulemaking procedure for a non-

controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on December 3, 1998. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on September 22, 1998.

Donald F. Hensley,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98-27251 Filed 10-8-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98-ACE-43]

Amendment to Class E Airspace; Meade, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends the Class E airspace area at Meade Municipal Airport, Meade, KS. The FAA has developed Global Positioning System (GPS) Runway (RWY) 17, GPS RWY 35, and Nondirectional Radio Beacon (NDB) RWY 17 Standard Instrument Approach Procedures (SIAPs) to serve Meade Municipal Airport, KS. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate these SIAPs and for Instrument Flight Rules (IFR) operations at this airport. The enlarged area will contain the new GPS RWY 17, GPS RWY 35, and NDB RWY 17 SIAPs in controlled airspace.

In addition, a minor revision to the geographic coordinates for the Airport Reference Point (ARP) is included in this document. The intended effect of this rule is to provide controlled Class E airspace for aircraft executing the GPS RWY 17, GPS RWY 35, and NDB RWY 17 SIAPs, revise the coordinates for the Meade Municipal Airport ARP, and to segregate aircraft using instrument approach procedures in instrument conditions from aircraft operating in visual conditions.

DATES: This direct final rule is effective on 0901 UTC, January 28, 1999.

Comments for inclusion in the Rules Docket must be received on or before November 25, 1998.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE-520, Federal Aviation Administration, Docket Number 98-ACE-43, 601 East 12th Street, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, MO 64106; telephone: (816) 426-3408.

SUPPLEMENTARY INFORMATION: The FAA has developed GPS RWY 17, GPS RWY 35, and NDB RWY 17 SIAPs to serve the Meade Municipal Airport, Meade, KS. The Class E airspace includes a minor revision to the geographic coordinates for the Meade Municipal Airport ARP. The amendment to Class E airspace at Meade, KS, will provide additional controlled airspace at and above 700 feet AGL in order to contain the new SIAPs within controlled airspace, and thereby facilitate separation of aircraft operating under Instrument Flight Rules. The 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 7400.9F, dated September 10, 1998, and effective September 16, 1998, 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. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement

weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. 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

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 98-ACE-43." The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, 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 Meade, KS [Revised]

Meade Municipal Airport, KS
(Lat. 37°16'37" N., long. 100°21'23" W.)
Meade NDB

(Lat. 37°17'03" N., long. 100°21'31" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Meade Municipal Airport and within 2.5 miles each side of the 009° bearing from the Meade NDB extending from the 6.5-mile radius to 7 miles north of the airport.

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Issued in Kansas City, MO, on September 23, 1998.

Donovan D. Schardt,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98-27249 Filed 10-8-98; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Ivermectin

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 for use of ivermectin Type A medicated articles to make Type B and C medicated swine feeds, to make Type C feed for treatment and control of threadworms (*Strongyloides ransomi*), and as top-dressing for individual treatment of adult swine.

EFFECTIVE DATE: October 9, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, is sponsor of NADA 140-974 that provides for use of Ivomec (ivermectin 0.6%) Type A articles to make ivermectin Type B and C swine feeds. The Type C feeds contain 1.8 grams ivermectin per ton for feeding to weaned, growing and finishing swine, and adult and breeding swine. It is used for treatment and control of gastrointestinal roundworm, kidney worm, and lungworm infections, and lice and mite infestations. The supplemental NADA provides for use of the Type C feeds for treatment and control of threadworms (*Strongyloides ransomi*) infections, specifically treatment and control of "threadworms

(*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation)," and for use as top-dressing for individual treatment of adult swine. The supplemental NADA is approved as of August 10, 1998, and the regulations are amended in § 558.300 (21 CFR 558.300) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.300 is amended by redesignating paragraph (c) as paragraph (d), adding new paragraph (c), and in newly redesignated paragraph (d) inserting several editorial and technical changes and adding a required limitation statement.

This supplemental NADA is for use of approved ivermectin Type A medicated articles to make Type B and C medicated feeds. Ivermectin is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved medicated feed application is required for making Type B or C medicated feeds as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by the requirement for feed mill licenses. Therefore, use of ivermectin Type A medicated articles to make Type B and C medicated feeds as provided in this NADA is limited to manufacture in a licensed feed mill.

Also, the regulation concerning tolerances for ivermectin residues in edible tissues is amended to provide for an acceptable daily intake (ADI) for total ivermectin residues. The ADI is the amount of total drug residue that can be safely consumed by humans every day. Previously, FDA had codified safe concentrations for drug residues. The safe concentrations were confusing because few individuals understood the relationship between safe concentrations, a value representing total residues, and tolerances, the part of the drug residue in a given tissue that is detected by a specific analytical method. To eliminate this confusion, FDA is codifying the ADI.

In addition, the regulations for tolerances for ivermectin residues is further amended to establish a tolerance for ivermectin residues in swine muscle.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 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, this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 10, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use in swine for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation).

FDA has determined under 21 CFR 25.33(a)(1) and (a)(7) 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.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.344 is revised to read as follows:

§ 556.344 Ivermectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

(b) *Tolerances—*(1) *Liver.* A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in liver (target tissue) as follows:

(i) *Cattle.* 100 parts per billion.