

Designated as Surface Areas” to read “Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.”

Issued in Kansas City, MO, on May 8, 2003.

**David W. Hope,**

*Acting Manager, Air Traffic Division, Central Region.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2003-15075; Airspace Docket No. 03-ACE-43]

#### Modification of Class E Airspace; Valentine, NE

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** An Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 14 ORIGINAL Standard Instrument Approach Procedure (SIAP) has been developed to serve Miller Field, Valentine, NE. This action expands Class E airspace extending upward from 700 feet above ground level (AGL) at Valentine, NE to contain aircraft executing the approach. The Miller Field airport reference point has been redefined and is incorporated into the legal description of Valentine, NE Class E airspace.

**DATES:** This direct final rule is effective on 0901 UTC, September 4, 2003. Comments for inclusion in the Rules Docket must be received on or before June 25, 2003.

**ADDRESSES:** Send comments on this regulation 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-2003-15075/ Airspace Docket No. 03-ACE-43, 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:** The amendment to 14 CFR part 71 modifies the Class E airspace area at Valentine, NE. An RNAV (GPS) RWY 14 ORIGINAL SIAP has been developed to serve Miller Field, Valentine, NE. The SIAP requires additional controlled airspace to contain aircraft executing the approach procedure. This action expands Class E airspace extending upward from 700 feet AGL at Valentine, NE. The National Aeronautical Charting Office redefined the Valentine, Miller Field, NE airport reference point effective April 9, 2003. Class E controlled airspace at Valentine, NE is defined, in part, by the Miller Field airport reference point. This action corrects discrepancies between the previous and revised airport reference points by modifying the Valentine, NE Class E airspace area. It incorporates the revised Miller Field airport reference point in the Class E airspace legal description and brings the airspace area into compliance with FAA Order 7400.2E, Procedures for Handling Airspace Matters. 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 7400.9K, dated August 30, 2002, and effective September 16, 2002, 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-2003-15075/Airspace Docket No. 03-ACE-43.” 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 7400.9K, dated August 30, 2002, and effective September 16, 2002, 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 Valentine, NE**

Valentine, Miller Field, NE

(Lat. 42°51'28" N., long. 100°32'51" W.)

Valentine NDB

(Lat. 42°51'42" N., long. 100°32'59" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Miller Field; and within 2.6 miles each side of the 149° bearing from the Valentine NDB extending from the 6.5-mile radius to 7.9 miles southeast of the airport; and within 1.8 miles each side of the 325° bearing from the airport extending from the 6.5-mile radius to 9.2 miles northwest of the airport.

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**David W. Hope,**

*Acting Manager, Air Traffic Division, Central Region.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 522**

**Injectable or Implantable Dosage Form New Animal Drugs; Zinc Gluconate**

**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 new animal drug application (NADA) filed by Technology Transfer, Inc. The NADA provides for use of zinc gluconate solution for chemical sterilization of dogs by intratesticular injection.

**DATES:** This rule is effective May 19, 2003.

**FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

Technology Transfer, Inc., 33 East Broadway, suite 190, Columbia, MO 65203, filed NADA 141–217 that provides for use of NEUTERSOL (zinc gluconate neutralized by arginine) Injectable Solution for chemical sterilization of 3- to 10-month-old male dogs by intratesticular injection. The NADA is approved as of March 17, 2003, and the regulations are amended in 21 CFR part 522 by adding new § 522.2690 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Technology Transfer, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 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)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 17, 2003.

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**

**21 CFR Part 510**

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

**21 CFR Part 522**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Technology Transfer, Inc.” and in the table in paragraph (c)(2) by numerically adding an entry for “067647” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

Firm name and address	Drug labeler code
* * *	* *
Technology Transfer, Inc., 33 East Broadway, suite 190, Columbia, MO 65203.	067647
* * *	* *

(2) \* \* \*

Drug labeler code	Firm name and address
* *	* *
067647	Technology Transfer, Inc., 33 East Broadway, suite 190, Columbia, MO 65203.
* *	* *

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Section 522.2690 is added to read as follows: