

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

David W. Hope,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 03–12379 Filed 5–16–03; 8:45 am]

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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*.

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:

§ 522.2690 Zinc gluconate.

(a) *Specifications.* Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) *Sponsor.* See No. 067647 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) *Indications for use.* Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 12, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-12368 Filed 5-16-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY**31 CFR Part 103****Notice of Temporary Extension of Conditional Exception to Bank Secrecy Act Regulations Relating to Orders for Transmittal of Funds by Financial Institutions**

AGENCY: Financial Crimes Enforcement Network (“FinCEN”), Treasury.

ACTION: Extension of conditional exception.

SUMMARY: FinCEN is giving notice that it is extending, until December 1, 2003, a conditional exception to a Bank Secrecy Act requirement that is due to expire on May 31, 2003. The exception permits financial institutions to substitute coded information for the true name and address of a customer in a funds transmittal order. The purpose of the extension is to permit FinCEN to perform a study of the alternatives to continuing the conditional exception.

DATES: Effective June 1, 2003.

FOR FURTHER INFORMATION CONTACT: David Vogt, Executive Associate Director, Office of Regulatory Programs, FinCEN, (202) 354-6400, or Judith R. Starr, Chief Counsel, FinCEN, (703) 905-3590.

SUPPLEMENTARY INFORMATION:**I. Background**

In 1998, FinCEN granted a conditional exception (“the CIF Exception”) to the strict operation of 31 CFR 103.33(g) (the “Travel Rule”). See FinCEN Issuance 98-1, 63 FR 3640 (January 26, 1998).

The Travel Rule requires a financial institution to include certain information in transmittal orders relating to transmittals of funds of \$3,000 or more. The CIF Exception addressed computer programming problems in the banking and securities industries by relaxing the Travel Rule’s requirement that a customer’s true name and address be included in a funds transmittal order, so long as alternate steps, described in FinCEN Issuance 98-1 and designed to prevent avoidance of the Travel Rule, were satisfied. By its terms, the CIF Exception to the Travel Rule was to expire on May 31, 1999; however, in light of programming burdens associated with year 2000 compliance issues, FinCEN extended the CIF Exception so that it would expire on May 31, 2001. See FinCEN Issuance 99-1, 64 FR 41041 (July 29, 1999). On May 30, 2001, after first soliciting input from the law enforcement community for its views on any law enforcement burdens caused by the CIF Exception, FinCEN again extended the CIF Exception. The CIF Exception is scheduled to expire on May 31, 2003. See FinCEN Issuance 2001-1, 66 FR 32746 (June 18, 2001). On March 7, 2003, FinCEN published a Notice of intent to permit the CIF exception to expire on May 31, 2003. The Notice solicited comment on four issues:

(1) Whether there are technological barriers to full compliance with the Travel Rule;

(2) Whether financial institutions will require additional time to comply;

(3) Whether the exception has had an adverse effect on law enforcement investigations; and

(4) Whether there is a potential for abuse of the exception.

II. The CIF Exception

FinCEN promulgated the Travel Rule in 1995. The Travel Rule requires financial institutions to include certain information in transmittal orders relating to transmittals of funds of \$3,000 or more, which must “travel” with the order throughout the funds transmittal sequence. Among these requirements is that each transmittor’s financial institution and intermediary financial institution include in a transmittal order the transmittor’s true name and street address. See 31 CFR 103.33(g)(1)(i)-(ii) and (g)(2)(i)-(ii). Subsequently, financial institutions represented to FinCEN that their ability to comply with the Travel Rule at all depended on their ability to use their automated customer information files, known as CIFs. Although an originating institution always knew the originating

customer’s true name and address, the CIFs were often programmed with coded or nominee names and addresses (or post office boxes). The reprogramming tasks involved in changing the CIFs were represented to be a significant barrier to compliance with the Travel Rule. In light of these burdens, and in the interest of obtaining prompt compliance, FinCEN promulgated the conditional exception.

The conditional exception provides that a financial institution may satisfy the requirements of 31 CFR 103.33(g) that a customer’s true name and address be included in a transmittal order, only upon satisfaction of the following conditions:

(1) The CIFs are not specifically altered for the particular transmittal of funds in question;

(2) The CIFs are generally programmed and used by the institution for customer communications, not simply for transmittal of funds transactions, and as so programmed generate other than true name and street address information;

(3) The institution itself knows and can associate the CIF information used in the funds transmittal order with the true name and street address of the transmittor of the order;

(4) The transmittal order includes a question mark symbol immediately following any designation of the transmittor other than by a true name on the order;

(5) Any currency transaction report or suspicious activity report by the institution with respect to the funds transmittal contains the true name and address information for the transmittor and plainly associates the report with the particular funds transmittal in question.

The conditional exception further provides that it has no application to any funds transmittals for whose processing an institution does not automatically rely on preprogrammed and prespecified CIF name and address information. FinCEN’s release promulgating the CIF Exception further warned financial institutions that any customer request for a nominee name in a CIF should be carefully evaluated as a potentially suspicious transaction. See 63 FR 3642.

III. Comments Received on the Expiration of the CIF Exception

The comment period closed on April 21, 2003. FinCEN received 16 comments from banks, trade groups, financial consultants, the Federal Reserve’s Wholesale Products Branch, and the Department of Justice, reflecting a diversity of views. Eight commenters