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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Effective Date 5-16-03

Publication Date 5-19-03

Certifier Jen Cooke

Injectable or Implantable Dosage Form New Animal Drugs; Zinc Gluconate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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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 [*insert date of publication in the Federal Register*].

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.

cv0318

NADA 141-217

NFR 1

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.

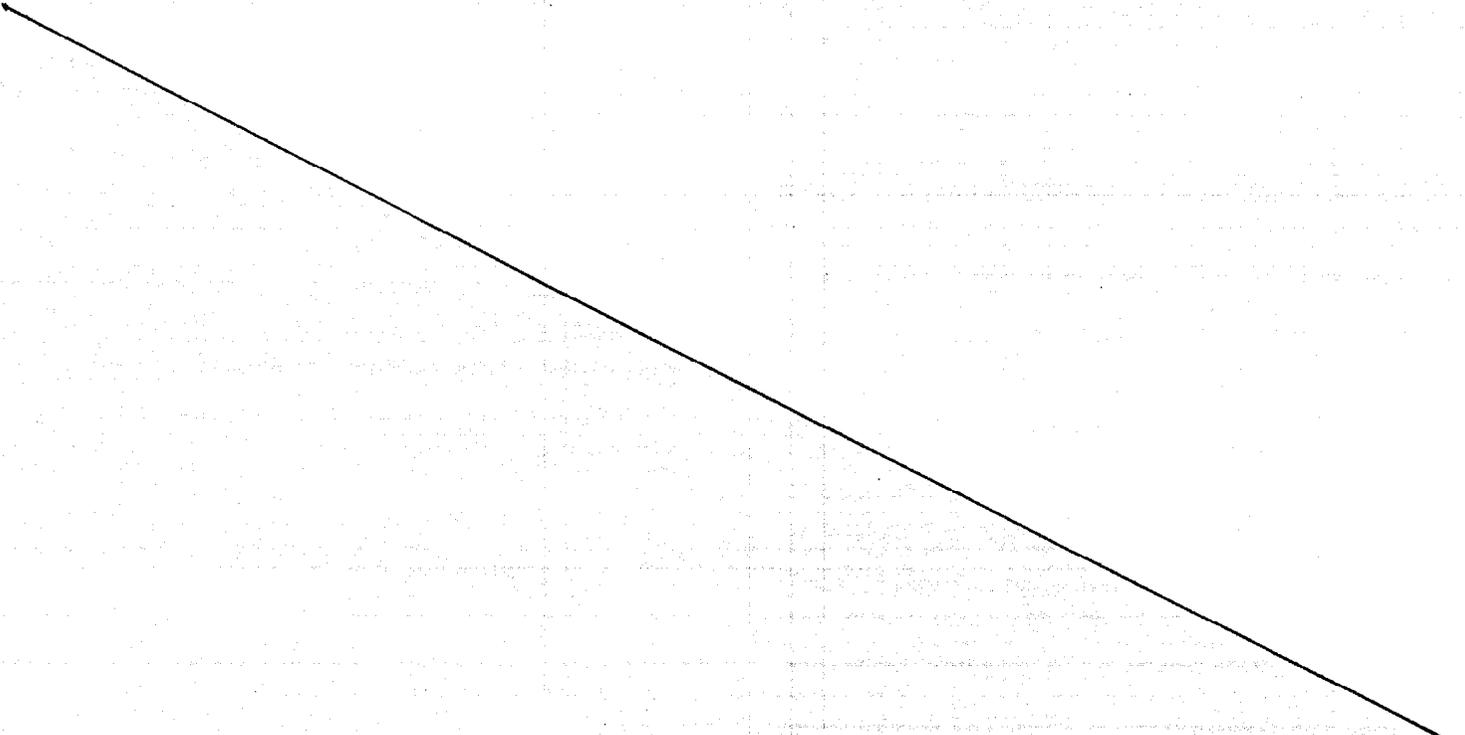
(a) *Specifications.* Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(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: 5/12/03
May 12, 2003.

SFSK

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.
[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

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Jan Cooke