Drug labeler code	Firm name and address
* * * *	* * *
062240	Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027
* * * *	* * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.260 [Amended]

4. Section 520.260 *n-Butyl chloride capsules* is amended in paragraph (b)(2) by removing ''012983'' and adding in its place ''038782''.

§ 520.2184 [Amended]

5. Section 520.2184 *Sodium sulfachloropyrazine monohydrate* is amended in paragraph (b) by removing the phrase ''Nos. 010042 and 053501'' and adding in its place ''No. 010042''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

6–7. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.723 [Amended]

8. Section 522.723 *Diprenorphine hydrochloride injection* is amended in pargraph (c) by removing ''010042'' and adding in its place ''053923''.

§ 522.800 [Amended]

9. Section 522.800 *Droperidol and fentanyl citrate injection* is amended in pargraph (b) by removing ''000045'' and adding in its place ''000061''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

10. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.140 [Amended]

11. Section 558.140 *Chlortetracycline and sulfamethazine* is amended in paragraph (a) by removing ''000004'' and adding in its place ''063238''.

§ 558.485 [Amended]

12. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraph (a)(17).

§ 558.635 [Amended]

13. Section 558.635 *Virginiamycin* is amended in paragraph (b)(2) by removing ''011490'' and adding in its place ''046573''.

Dated: March 23, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–7925 Filed 3–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine Tablets and Boluses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify an approved new animal drug application (NADA) held by Pfizer, Inc. The NADA provides for use of sulfadimethoxine (SDM) tablets to treat bacterial infections of dogs and cats.

EFFECTIVE DATE: April 1, 1999.

FOR FURTHER INFORMATION CONTACT: Diane T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 15–102 that provides for oral use of SDM tablets for the treatment of SDM-susceptible bacterial infections of dogs and cats. The NADA was approved on December 14, 1964, for Hoffmann LaRoche, Inc. After several changes of sponsors, the current sponsor of the NADA, Pfizer, Inc., has filed a supplement to NADA 15–102 providing information supporting prior approval of their NADA and has requested codification. FDA concurs that NADA 15–102 was approved for use in dogs and cats on December 14, 1964, and therefore, amends 21 CFR 520.2220b to reflect the approval. Also, FDA is amending the regulation to add several editorial changes by removing paragraph (a), by redesignating paragraphs (b), (d), and (e) as paragraphs (a), (b), and (d), respectively, and by revising new paragraphs (a) and (d)(2) to reflect the codification.

Approval of this supplemental NADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(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.

List of Subject 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 520.2220b is amended by removing paragraph (a), by redesignating paragraphs (b), (d), and (e) as paragraphs (a), (b), and (d), respectively, and by revising newly redesignated paragraphs (a) and (d)(2) to read as follows:

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(2) To 000061, approval for use as in paragraph (d)(2).

* * * * *

(d) * * *

(2) *Dogs and cats.* (i) *Amount.* 12.5 to 25 milligrams per pound of body weight.

(ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

(iii) *Limitations.* Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

Dated: March 17, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–7924 Filed 3–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dinoprost Tromethamine Sterile Solution

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intramuscular use of dinoprost tromethamine sterile solution in cattle, swine, and mares.

EFFECTIVE DATE: April 1, 1999

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–253 that provides for use of ProstaMate™ (dinoprost tromethamine injection) for intramuscular, veterinary prescription use for estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle; for abortion of feedlot and other nonlactating cattle; for parturition induction in swine; and for controlling the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

Approval of Phoenix's ANADA 200–253 for ProstaMate™ (dinoprost tromethamine injection) sterile solution is as a generic copy of Pharmacia & Upjohn's NADA 108–901 Lutalyse® (dinoprost tromethamine) sterile solution. ANADA 200–253 is approved as of February 12, 1999, and the regulations are amended in 21 CFR 522.690(b) 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 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.

The agency has determined under 21 CFR 25.33(a)(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.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.690 [Amended]

2. Section 522.690 *Dinoprost tromethamine sterile solution* is amended in paragraph (b) by removing ''No. 000009'' and adding in its place ''Nos. 000009 and 059130''.

Dated: March 18, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–7922 Filed 3–31–99; 8:45 am]

BILLING CODE 4160–01–F

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Chapter II

Establishment of Agency for International Development as an Executive Agency

AGENCY: U.S. Agency for International Development.

ACTION: Final rule.

SUMMARY: The U.S. Agency for International Development (''USAID'') is amending its chapter in the Code of Federal Regulations (''CFR'') to delete the reference to the U.S. International Development Cooperation Agency (''IDCA''). Under the provisions of the Foreign Affairs Reform and Restructuring Act of 1998, IDCA was abolished and USAID was established as an Executive agency, effective April 1, 1999.

DATES: Effective April 1, 1999.

FOR FURTHER INFORMATION CONTACT: Jan Miller, Office of General Counsel, 202–712–4174; jmiller @usaid.gov.

SUPPLEMENTARY INFORMATION: Under the provisions of the Foreign Affairs Reform and Restructuring Act of 1998, as contained in Public Law 105–277, IDCA was abolished and USAID was established as an Executive agency, effective April 1, 1999.

The abolition of IDCA does not affect the status and validity of USAID regulations, directives, rulings, policies; they continue in effect.

This is a procedural rule exempt from notice and comment under 5 U.S.C. 533(b)(3)(a). This rule is not a significant rule for purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. This rule does not have a significant impact on small business entities under the Regulatory Flexibility Act.

For the reasons set forth in the preamble and under the authority of 22 U.S.C. 2381, revise the heading of chapter II of title 22 of the Code of Federal Regulations to read as follows:

CHAPTER II—AGENCY FOR INTERNATIONAL DEVELOPMENT

Singleton B. McAllister,

General Counsel.

[FR Doc. 99–7968 Filed 3–31–99; 8:45 am]

BILLING CODE 6116–01–M