summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (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.

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 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add a new entry for ''Modern Veterinary Therapeutics, LLC''; and in the table in paragraph (c)(2) numerically add a new entry for ''015914'' 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 |
|---|---|
| * * * * * | |
| Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157. | 015914 |
| * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * | * * * |
| 015914 | Modern Veterinary Therapeutics, LLC, 18301 SW. 86th Ave., Miami, FL 33157 |
| * * | * * * |

## 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. Revise § 522.775 to read as follows:

**§ 522.775 Doxapram.**

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) doxapram hydrochloride.

(b) *Sponsor.* See Nos. 000856 and 015914 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (/lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

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

Dated: December 19, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E6–22510 Filed 12–29–06; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Clomipramine Tablets

**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 Novartis Animal Health US, Inc. The supplemental NADA adds a 5-milligram tablet size of clomipramine hydrochloride, used in dogs for treatment of separation anxiety.

**DATES:** This rule is effective January 4, 2007.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 141–120 that provides for the veterinary prescription use of CLOMICALM (clomipramine hydrochloride) Tablets for treatment of separation anxiety in dogs. The supplement provides for a 5-milligram tablet size of clomipramine hydrochloride. The supplemental NADA is approved as of November 22, 2006, and 21 CFR 520.455 is amended 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 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 Division of Dockets Management (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.

FDA 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.

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 in 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. In § 520.455, revise the section heading and paragraph (a) to read as follows:

**§ 520.455 Clomipramine tablets.**

(a) Specifications. Each tablet contains 5, 20, 40, or 80 milligrams (mg) clomipramine hydrochloride.

* * * * *

Dated: December 19, 2006.

**Steven D. Vaughn,**

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

[FR Doc. E6–22509 Filed 1–3–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Florfenicol

**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 Schering-Plough Animal Health Corp. The supplemental NADA revises the nomenclature for a respiratory pathogen in the label claim for florfenicol when used in swine drinking water for the treatment of respiratory disease.

**DATES:** This rule is effective January 4, 2007.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 556 Morris Ave., Summit NJ 07901, filed a supplement to NADA 141–206 for NUFLOR (florfenicol) 2.3% Concentrate Solution used to make medicated drinking water for administration to swine for the treatment of respiratory disease associated with several bacterial pathogens. The supplemental NADA revises the nomenclature for a respiratory pathogen in the label claim. The supplemental NADA is approved as of December 8, 2006, and the regulations in 21 CFR 520.955 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. 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.

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 in 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.

**§ 520.955 [Amended]**

■ 2. In paragraph (d)(2) of § 520.955, remove the words ''Type 2''.

Dated: December 21, 2006.

**Steven D. Vaughn,**

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

[FR Doc. E6–22516 Filed 12–29–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Dirlotapide

**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 Pfizer, Inc. The NADA provides for the veterinary prescription use of dirlotapide solution in dogs for the management of obesity.

**DATES:** This rule is effective January 4, 2007.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed NADA 141–260 for SLENTROL (dirlotapide) Oral Solution. The NADA provides for the veterinary prescription use of dirlotapide solution in dogs for the management of obesity. The application is approved as of December 12, 2006, and the regulations are amended in 21 CFR part 520 by adding new § 520.666 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 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 Division of Dockets Management (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 (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of