in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 178**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

## PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS.

1. The authority citation for 21 CFR part 178 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine (CAS Reg. No. 182635–99–0). | For use as an ultraviolet (UV) stabilizer only at levels not to exceed 0.33 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 1.2, and 1.3, under conditions of use D, E, F, and G, as described in Table 2 of § 176.170 of this chapter. |
| * * * | * * * * |

Dated: August 26, 1999.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 99–23000 Filed 9–2–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510 and 522

### Implantation or Injectable Dosage Form New Animal Drugs; Estradiol and Testosterone, Progesterone and Estradiol, Trenbolone, and Trenbolone and Estradiol, With Tylosin

**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 four supplemental applications filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc., two supplemental new animal drug applications (NADA's) and two supplemental abbreviated new animal drug applications (ANADA's). The supplemental applications provide for addition of tylosin as a local antibacterial to estradiol/testosterone, progesterone/estradiol, trenbolone, and trenbolone/estradiol cattle ear implants. The products are subcutaneous implants for cattle for weight gain and/or feed efficiency.

**EFFECTIVE DATE: SEPTEMBER 3, 1999.**

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed the following applications:

Supplemental NADA 110–315 for Component® E–S with Tylan® implant (200 milligrams (mg) progesterone and 20 mg estradiol benzoate in eight pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain and improved feed efficiency in steers weighing 400 pounds (lb) or more, and Component E–C® with Tylan® implant (100 mg progesterone and 10 mg estradiol benzoate in four pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain in suckling beef calves up to 400 lb of body weight.

Supplemental NADA 135–906 for Component® E–H with Tylan® implant (20 mg estradiol benzoate and 200 mg testosterone propionate in eight pellets with 29 mg tylosin tartrate in one pellet) for growth promotion and improved feed efficiency in heifers weighing 400 lb or more.

Supplemental ANADA 200–221 for Component® TE–S with Tylan® implant (120 mg trenbolone acetate and 24 mg estradiol in six pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain and improved feed efficiency in feedlot steers.

Supplemental ANADA 200–224 for Component® T–S with Tylan® implant and Component® T–H with Tylan® implant. Component® T–S with Tylan® implant contains 140 mg trenbolone acetate in seven pellets and 29 mg tylosin tartrate in one pellet. It is used for improved feed efficiency in growing-finishing feedlot steers. It should be reimplanted once after 63 days. Component® T–H with Tylan® implant contains 200 mg trenbolone acetate in 10 pellets and 29 mg tylosin tartrate in 1 pellet. It is used for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers. It should be used in feedlot heifers only, during approximately the last 63 days prior to slaughter.

The supplements are approved as of July 20, 1999, and the regulations are amended in § 522.842 (21 CFR 522.842) and 21 CFR 522.1940, 522.2476, and 522.2477 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

Also, § 522.842 is amended to remove several outdated paragraphs.

In addition, the sponsor has informed FDA of the change of corporate name to Ivy Laboratories, Div. of Ivy Animal Health, Inc. FDA is amending 21 CFR 510.600(c) to reflect the new name.

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 each supplement 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals for food producing animals qualify for 3 years of marketing exclusivity beginning July 20, 1999, because the supplemental applications contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approvals and conducted or sponsored by the applicant. The 3 years of marketing exclusivity apply only to the addition of tylosin tartrate to the implants as a local antibacterial.

FDA has carefully considered the potential environmental effects of these actions. FDA has concluded that the actions will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 practices and procedures, 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.

**§ 510.600 [Amended]**

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for ''Ivy Laboratories, Inc.'' and in paragraph (c)(2) in the entry for ''021641'' by removing the sponsor name and adding in its place ''Ivy Laboratories, Div. of Ivy Animal Health, Inc.''.

## 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 522.842 is amended by removing and reserving paragraph (a) and removing paragraph (e), by revising paragraph (b) and the introductory text of paragraph (d), by redesignating paragraph (d)(1) as paragraph (d)(1)(i) and by adding paragraph (d)(1)(ii) to read as follows:

**§ 522.842 Estradiol benzoate and testosterone propionate in combination.**

(a) [Reserved]

(b) *Sponsors.* See 000856 in § 510.600(c) of this chapter for use as in paragraph (d)(1)(i), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

(d) *Conditions of use—Heifers.* For implantation as follows:

(1) *Amount.* (i) 20 milligrams estradiol benzoate and 200 milligrams testosterone propionate in eight pellets per implant dose.

(ii) 20 milligrams estradiol benzoate and 200 milligrams testosterone propionate in eight pellets with 29 milligrams tylosin tartrate as a local antibacterial in one pellet, per implant dose.

* * * * *

5. Section 522.1940 is amended by revising paragraph (b); by redesignating paragraphs (d)(1)(i) and (d)(2)(i) as paragraphs (d)(1)(i)(A) and (d)(2)(i)(A); by revising newly redesignated (d)(1)(i)(A) and (d)(2)(i)(A); and by adding paragraphs (d)(1)(i)(B), and (d)(2)(i)(B) to read as follows:

**§ 522.1940 Progesterone and estradiol benzoate in combination.**

* * * * *

(b) *Sponsors.* See 000856 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(ii), (d)(2)(iii), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1) and (d)(2)(i) through (d)(2)(iii)(A) of this section.

* * * * *

(d) * * *

(1) *Suckling beef calves*—(i) *Amount.* (A) 100 milligrams of progesterone and 10 milligrams of estradiol benzoate in four pellets per implant dose.

(B) 100 milligrams of progesterone and 10 milligrams of estradiol benzoate in four pellets with 29 milligrams of tylosin tartrate as a local antibacterial in one pellet per implant dose.

* * * * *

(2) *Steers*—(i) *Amount*—(A) 200 milligrams of progesterone and 20 milligrams estradiol benzoate in eight pellets per implant dose.

(B) 200 milligrams progesterone and 20 milligrams estradiol benzoate in eight pellets with 29 milligrams tylosin tartrate as a local antibacterial in one pellet per implant dose.

* * * * *

6. Section 522.2476 is amended by revising paragraph (b), by redesignating the text of paragraphs (d)(1) and (d)(2) as paragraphs (d)(1)(i) and (d)(2)(i), and by adding paragraphs (d)(1)(ii) and (d)(2)(ii) to read as follows:

**§ 522.2476 Trenbolone acetate.**

* * * * *

(b) *Sponsors.* See 012579 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i), (d)(2)(i), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) 200 milligrams trenbolone acetate (10 pellets of 20 milligrams each) with 29 milligrams tylosin tartrate as a local antibacterial (1 pellet) per implant dose, for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers. Use last 63 days prior to slaughter.

(2) * * *

(ii) 140 milligrams trenbolone acetate (seven pellets of 20 milligrams each) with 29 milligrams tylosin tartrate as a local antibacterial (one pellet) per implant dose, for improved feed efficiency in growing-finishing feedlot steers. Use 126 days prior to slaughter. Should be reimplanted once 63 days prior to slaughter.

* * * * *

7. Section 522.2477 is amended by redesignating paragraphs (a), (b), (c), and (c)(1)(i) as paragraphs (b), (c), (d), and (d)(1)(i)(A); by reserving paragraph (a); by revising newly redesignated paragraph (b); and by adding paragraph (d)(1)(i)(B) to read as follows:

**§ 522.2477 Trenbolone acetate and estradiol.**

(a) [Reserved]

(b) *Sponsors.* See 012579 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) 120 milligrams trenbolone acetate and 24 milligrams estradiol in 6 pellets with 29 milligrams tylosin tartrate as a local antibacterial in 1 pellet per implant dose.

* * * * *

Dated: August 24, 1999.

**Claire M. Lathers,**

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

[FR Doc. 99–22995 Filed 9–2–99; 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; Enrofloxacin 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 Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for an additional tablet size for enrofloxacin tablets used in dogs and cats for the management of diseases associated with bacteria susceptible to enrofloxacin and for the removal of a tablet size no longer marketed.

**EFFECTIVE DATE:** September 3, 1999.

**FOR FURTHER INFORMATION CONTACT:** Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1705.

**SUPPLEMENTARY INFORMATION:** Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140–441 Baytril® tablets (enrofloxacin) that provides for 136-milligram (mg) tablet size in addition to 22.7- and 68.0-mg tablets. Furthermore, the sponsor stated that the 5.7-mg tablets are no longer marketed and has requested the size be deleted. The supplemental NADA is approved as of August 3, 1999, and the regulations are amended in 21 CFR 520.812(a) to reflect the approval.

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(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 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.

#### § 520.812 [Amended]

2. Section 520.812 *Enrofloxacin tablets* is amended in paragraph (a) by removing ''5.7, 22.7, or 68.0'' and adding in its place ''22.7, 68.0, or 136.0'' .

Dated: August 24, 1999.

**Claire M. Lathers,**

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

[FR Doc. 99–22998 Filed 9–3–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 556 and 558

### New Animal Drugs For Use In Animal Feeds; Semduramicin and Virginiamycin

**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 using approved single ingredient semduramicin and virginiamycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. Approval of the NADA also provides for tolerances for semduramicin residues and an acceptable daily intake (ADI) for semduramicin and for virginiamycin.

**EFFECTIVE DATE:** September 3, 1999.

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–114 that provides for combining approved Aviax® (22.7 grams per pound (g/lb) semduramicin) and Stafac® (20 or 227 g/lb virginiamycin) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The Type C medicated broiler feeds containing 25 parts per million (ppm) (22.7 g/ton (t)) semduramicin and 5 to 15 g/t virginiamycin are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain. The Type C medicated broiler feeds containing 25 ppm semduramicin and 5 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain and improved feed efficiency. The Type C medicated broiler feeds containing 25 ppm semduramicin and 20 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for prevention of necrotic enteritis caused by *Clostridium*