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Marion Blakey,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

New Animal Drugs; Neomycin Sulfate Soluble Powder

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 abbreviated new animal drug application (ANADA) filed by Alpharma, Inc. The supplemental ANADA provides for use of neomycin sulfate soluble powder in the drinking water of growing turkeys for the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin.

DATES: This rule is effective December 27, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to ANADA 200–130 that provides for use of NEO–SOL 50 (neomycin sulfate) soluble powder for making medicated drinking water for administration to cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin. The supplemental ANADA provides for use of neomycin in the drinking water of growing turkeys for the control of mortality associated with *E. coli* organisms susceptible to neomycin. The supplemental application is approved as of October 25, 2002, and the regulations are amended in 21 CFR 520.1484 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 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.

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.

§ 520.1484 [Amended]

2. Section 520.1484 *Neomycin sulfate soluble powder* is amended in paragraph (b)(1) by removing ''046573'' and in paragraph (b)(2) by adding in numerical sequence ''046573''.

Dated: December 17, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32748 Filed 12–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol Benzoate

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 Fort Dodge Animal Health. The supplemental NADA provides for use of an implant containing 100 milligrams (mg) trenbolone acetate and 14 mg estradiol benzoate for increased rate of weight gain in steers fed in confinement for slaughter.

DATES: This rule is effective December 27, 2002.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: dbenz@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141–043 for SYNOVEX (trenbolone acetate and estradiol benzoate) implants. The supplemental NADA provides for use of SYNOVEX Choice, an implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate, for increased rate of weight gain in steers fed in confinement for slaughter. The supplemental NADA is approved as of October 3, 2002, and the regulations are amended in 21 CFR 522.2478 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 supplemental 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning October 3, 2002.

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 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.

2. Section 522.2478 is revised to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications*. Each implant dose consists of:

(1) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(2) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*. (i) For an implant as described in paragraph (a)(1) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(C) *Limitations*. Implant subcutaneously in ear only.

(ii) For an implant as described in paragraph (a)(2) of this section:

(A) *Amount*. 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain.

(C) *Limitations*. Implant subcutaneously in ear only.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate (as described in paragraph (a)(1) of this section).

(ii) *Indications for use*. For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Not for dairy or beef replacement heifers.

Dated: December 17, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32750 Filed 12–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Danofloxacin

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 danofloxacin solution in cattle, by subcutaneous injection, for treatment of bovine respiratory disease associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*. FDA is also amending the regulations to add the acceptable daily intake for total residues of danofloxacin and tolerances for residues of danofloxacin in edible tissues of cattle.

DATES: This rule is effective December 27, 2002.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301–827–7576, e-mail: tletonja@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed NADA 141–207 for A180 (danofloxacin mesylate) Injectable Solution. The NADA provides for the veterinary prescription use of danofloxacin solution in cattle, by subcutaneous injection, for treatment of bovine respiratory disease associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*. The application is approved as of September 20, 2002, and the regulations are amended in 21 CFR part 522 by adding new § 522.522 and in 21 CFR part 556 by adding new § 556.169 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning September 20, 2002.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA'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 (see **ADDRESSES**) 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 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are 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.

2. Section 522.522 is added to read as follows:

§ 522.522 Danofloxacin.

(a) *Specifications*. Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia*