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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]

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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.