FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404–6402, is the sponsor of NADA 141–029 that provides for the use of Percorten™-V (desoxycorticosterone pivalate) as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of January 12, 1998, and the regulations are amended by adding new 21 CFR 522.535 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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.

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 for nonfood-producing animals qualifies for 5 years of marketing exclusivity beginning January 12, 1998, because no active ingredient of the drug (including any salt or ester of the active ingredient) has been approved in any other application.

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. New § 522.535 is added to read as follows:

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: February 6, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–6911 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Colistimethate Sterile 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 new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for subcutaneous use of colistimethate sodium powder, reconstituted in aqueous solution, in the neck of 1- to 3-day-old chickens.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–069 that provides for use of First Guard™ Sterile Powder (colistimethate sodium), reconstituted in sterile saline or sterile water for injection, for subcutaneous injection in the neck of 1- to 3-day-old chickens for control of early mortality associated with *Escherichia coli* organisms susceptible to colistin. The drug is restricted to use by or on the order of a licensed veterinarian. The NADA is approved as of January 13, 1998, and the regulations are amended by adding new § 522.468 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulations are amended by adding new § 556.167 to reflect that a tolerance for residues of colistimethate in edible chicken tissues is not required. The drug is a therapeutic product administered to 1- to 3-day-old chickens at the equivalent of 0.2 milligrams of colistin activity per chicken. At 28 days post-treatment, the earliest possible time broiler chickens would be considered marketable, total residues were calculated to be at least 36 times below the safe concentration level.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 for food-producing animals qualifies for 5 years of marketing exclusivity beginning January 13, 1998, because no active ingredient of the drug (including any ester or salt thereof) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action 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.

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 522.468 is added to read as follows:

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications*. Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor*. See 046573 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*. (1) 1- to 3-day-old chickens.

(i) *Dosage*. 0.2 milligram colistin activity per chicken.

(ii) *Indications for use*. Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations*. For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.167 is added to read as follows:

§ 556.167 Colistimethate.

A tolerance for residues of colistimethate in the edible tissues of chickens is not required.

Dated: February 22, 1998.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 98–6909 Filed 3–17–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Narasin, Bambermycins, and Roxarsone

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 Hoechst Roussel Vet. The NADA provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing narasin, bambermycins, and roxarsone.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2604.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed NADA 140–843 that provides for using approved single ingredient Type A medicated articles, Monteban® (45 grams (g) narasin activity per pound (/lb)), Flavomycin® (4 and 10 g bambermycins activity/lb), and 3–Nitro® (45.4, 90, and 227 g roxarsone/lb), to make Type C medicated broiler feeds containing 54 to 72 g narasin, 1 to 2 g bambermycins, and 22.7 to 45.4 g roxarsone/ton of feed. The Type C medicated broiler feed is used for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima*, and *E. brunetti*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens. NADA 140–843 is approved as of March 18, 1998.

Accordingly §§ 558.363 and 558.366 (21 CFR 558.363 and 558.366) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary. In addition, 21 CFR 558.95(d)(5) is amended by adding new paragraph (d)(5)(iii) to provide a cross-reference to the 3-way combination drug Type C medicated feed.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. to 4 p.m., Monday through Friday.

This approval is for use of approved Type A medicated articles to make combination Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required for making a Type B or Type C medicated feed as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of narasin, bambermycins, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in NADA 140–843 requires a feed mill license rather than an approved FDA Form 1900.

Under section 512(c)(2)(F)(ii) of the act, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 18, 1998 because the application contains 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 approval and conducted or sponsored by the applicant.

FDA has determined under 21 CFR 25.33(a)(2) 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 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner