acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid.

(b) The additive is used as an antimicrobial agent on red meat carcasses in accordance with current industry practice where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid and the maximum concentration of hydrogen peroxide is 75 ppm.

(c) The concentrations of peroxyacids and hydrogen peroxide in the additive are determined by a method entitled ''Hydrogen Peroxide and Peracid (as Peracetic Acid) Content,'' dated July 26, 2000, developed by Ecolab, Inc., which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of this method from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: November 14, 2000.

L. Robert Lake,

Director of Regulations Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–30050 Filed 11–24–00; 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; Ivermectin Paste

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of ivermectin oral paste for the treatment and control of various species of harmful gastrointestinal parasites in horses.

DATES: This rule is effective November 27, 2000.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–286 that provides for use of PHOENECTIN™ (ivermectin) Paste 1.87%. The ANADA provides for oral use of ivermectin paste for the treatment and control of various species of harmful gastrointestinal parasites in horses. The ANADA is approved as a generic copy of Merial Ltd.'s NADA 134–314 for EQVALAN® (ivermectin) Paste for Horses. ANADA 200–286 is approved as of September 20, 2000, and the regulations are amended in 21 CFR 520.1192 to reflect the approval. The basis for 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.

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.

2. Section 520.1192 is amended by revising paragraphs (a) and (b), by redesignating paragraph (c) as paragraph (d), and by adding new paragraph (c) to read as follows.

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram of paste contains 0.0187 milligram (1.87 percent) or 0.00153 milligram (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 050604 for use of a 1.87 percent paste as in paragraph (d)(1) of this section and a 0.153 percent paste as in paragraph (d)(2) of this section.

(2) No. 059130 for use of a 1.87 percent paste as in paragraph (d)(1) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

* * * * *

Dated: October 16, 2000.

Stephen S. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–30048 Filed 11–24–00; 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; Nitenpyram 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 new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the oral use of nitenpyram tablets for the treatment of flea infestations in dogs, puppies, cats, and kittens that are 4 weeks of age and older and 2 pounds (lb) of body weight or greater.

DATES: This rule is effective November 27, 2000.

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.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–175 that provides for the over-the-counter use of CAPSTAR™ (nitenpyram) tablets for the oral treatment of flea infestations on dogs,

puppies, cats, and kittens that are 4 weeks of age and older and 2 lb of body weight or greater. The NADA is approved as of October 20, 2000, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.1510 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 Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning October 20, 2000, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

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.

2. Section 520.1510 is added to read as follows:

§ 520.1510 Nitenpyram.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams of nitenpyram.

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

(c) [Reserved]

(d) *Conditions of use—Dogs and cats*—(1) *Amount.* One tablet given orally, as needed.

(2) *Indications for use.* For the treatment of flea infestations on dogs, puppies, cats, and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

Dated: November 8, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–30047 Filed 11–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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

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 Ivy Laboratories, Inc. The supplemental ANADA provides for adding tylosin tartrate as a local antibacterial to an approved subcutaneous cattle ear implant containing trenbolone and estradiol used in pasture cattle for increased rate of weight gain.

DATES: This regulation is effective November 27, 2000.

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.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200–221 for COMPONENT® TE–G (trenbolone acetate/estradiol) with Tylan®, a subcutaneous ear implant containing 40 of milligrams (mg) trenbolone acetate and 8 mg of estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol, and an additional pellet containing 29 mg of tylosin tartrate as a local antibacterial. The implants are used in pasture cattle (slaughter, stocker, and feeder steers and heifers) for increased rate of weight gain. The supplemental application is approved as of September 18, 2000, and the regulations are amended in 21 CFR 522.2477 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 18, 2000, 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 the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the addition of tylosin tartrate to the implant for which the supplemental application was approved.

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.