contact for correspondence between the FAA and the certificate holder and the name and mailing address of the certificate holder's agent for service.

(2) Other business names under which the certificate holder may operate.

(3) Reference to the economic authority issued by the Department of Transportation, if required.

(4) Type of aircraft, registration markings, and serial number of each aircraft authorized for use.

(i) Subject to the approval of the Administrator with regard to form and content, the certificate holder may incorporate by reference the items listed in paragraph (b)(4) of this section into the certificate holder's operations specifications by maintaining a current listing of those items and by referring to the specific list in the applicable paragraph of the operations specifications.

(ii) The certificate holder may not conduct any operation using any aircraft not listed.

(5) Kinds of operations authorized.

(6) Authorization and limitations for routes and areas of operations.

(7) Special airport authorizations and limitations.

(8) Time limitations, or standards for determining time limitations, for overhauling, inspecting, and checking airframes, engines, propellers, appliances, and emergency equipment.

(9) Authorization for the method of controlling weight and balance of aircraft.

(10) Aircraft wet lease information required by § 119.53(c).

(11) Any authorization or requirement to conduct supplemental operations as provided by § 119.21(a)(3).

(12) Any authorized deviation or exemption from any requirement of this chapter.

(13) An authorization permitting, or a prohibition against, accepting, handling, and transporting materials regulated as hazardous materials in transport under 49 CFR parts 171 through 180.

(14) Any other item the Administrator determines is necessary.

* * * * *

Issued in Washington, DC on May 7, 2010.

Pamela Hamilton-Powell,

Director, Office of Rulemaking, Aviation Safety.

[FR Doc. 2010–11266 Filed 5–11–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2010–N–0002]

Oral Dosage Form New Animal Drugs; Orbifloxacin Suspension

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 Intervet, Inc. The NADA provides for the veterinary prescription use of an oral suspension containing orbifloxacin for the treatment of various bacterial infections in dogs and cats.

DATES: This rule is effective May 12, 2010.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed NADA 141–305 that provides for veterinary prescription use of ORBAX (orbifloxacin) Oral Suspension for the treatment of various bacterial infections in dogs and cats. The NADA is approved as of March 25, 2010, and the regulations are amended in 21 CFR part 520 by adding new § 520.1618 to reflect the approval.

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 Division of Dockets Management (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.

FDA has determined under 21 CFR 25.33 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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 the 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.

§ 520.1616 [Amended]

■ 2. Revise the section heading of § 520.1616 to read "Orbifloxacin tablets.".

■ 3. Add § 520.1618 to read as follows:

§ 520.1618 Orbifloxacin suspension.

(a) *Specifications*. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) *Sponsor*. See No. 000061 in 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) *Indications for use*. For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Proteus mirabilis*, *Escherichia coli,* and *Enterococcus faecalis* and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, coagulase-positive staphylococci, *Pasteurella multocida*, *Proteus mirabilis*, *Pseudomonas* spp., *Klebsiella pneumoniae*, *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *E. faecalis*, β-hemolytic streptococci (Group G), and *Streptococcus equisimilis*.

(2) *Cats*—(i) *Amount*. 3.4 mg/lb (7.5 mg/kg) of body weight once daily.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by

susceptible strains of *S. aureus*, *E. coli*, and *P. multocida*.

Dated: May 6, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–11245 Filed 5–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2010–N–0002]

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 Sparhawk Laboratories, Inc. The ANADA provides for use of an ivermectin injectable solution in cattle and swine for treatment and control of various internal and external parasites.

DATES: This rule is effective May 12, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200–429 for the use of Ivermectin Injection in cattle and swine for treatment and control of various internal and external parasites. Sparhawk Laboratories, Inc.'s, Ivermectin Injection is approved as a generic copy of Merial Ltd.'s IVOMEC Injection for Cattle and Swine, approved under NADA 128–409. The ANADA is approved as of March 26, 2010, and the regulations in 21 CFR 522.1192 are amended to reflect the approval.

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 Division of Dockets Management (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 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. In § 522.1192, revise paragraphs (b)(1), (b)(2), and (e)(2)(ii) to read as follows:

§ 522.1192. Ivermectin

* * * * *

(b)* * *

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 055529, 058005, and 059130 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

* * * * *

(e) * * *

(2) * * *

(ii) *Indications for use*. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*scabies*) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For control of infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

* * * * *

Dated: May 7, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–11282 Filed 5–11–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA–2010–N–0002]

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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 First Priority, Inc. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a topical solution of ivermectin.

DATES: This rule is effective May 12, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123, filed a supplement to ANADA 200–340 for PRIVERMECTIN (ivermectin), a topical solution used on cattle to control infestations of certain species of external and internal parasites. The supplemental ANADA