generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the APA. 5 U.S.C. 551. NCUA has requested a SBREFA determination from the Office of Management and Budget, which is pending. As required by SBREFA, NCUA will file the appropriate reports with Congress and the General Accounting Office so that the final rule may be reviewed.

List of Subjects

12 CFR Part 745

Credit unions, Share insurance.

12 CFR Part 747

Administrative practice and procedure, Bank deposit insurance, Claims, Credit unions, Equal access to justice, Investigations, Lawyers, Penalties.

■ Accordingly, NCUA adopts as final the interim rule amending 12 CFR parts 745 and 747.

By the National Credit Union Administration Board on March 1, 2007.

Mary F. Rupp,

Secretary of the Board.

[FR Doc. E7–4225 Filed 3–8–07; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole 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 two supplemental new animal drug applications (NADAs) filed by Intervet, Inc. The supplemental NADAs provide for a revised human food safety warning for fenbendazole paste, used for the control of various internal parasites in horses and cattle.

DATES: This rule is effective March 9, 2007.

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, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 120–648 that provides for use of PANACUR (fenbendazole) Paste in horses for the control of various internal parasites, and to NADA 132–872 that provides for use of SAFE-GUARD (fenbendazole) Paste in cattle for the control of various internal parasites. The supplemental NADAs provide for a revised human food safety warning on product labeling. The supplemental NADAs are approved as of February 8, 2007, and the regulations are amended in 21 CFR 520.905c to reflect the approval and a current format.

Approval of these supplemental NADAs did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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.

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.

■ 2. Amend § 520.905c as follows:
■ a. Revise paragraph (a);
■ b. Redesignate paragraph (d) as paragraph (e);
■ c. Add new paragraph (d); and
■ d. Revise newly redesignated paragraph (e).

The revisions, redesignation, and addition read as follows:

§ 520.905c Fenbendazole paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Indications for use and amounts*—(A) For control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*): 2.3 mg per pound (/lb) of body weight, or for foals and weanlings (less than 18 months of age), 4.6 mg/lb of body weight. Retreatment at intervals of 6 to 8 weeks may be required.

(B) For control of arteritis caused by the fourth-stage larvae of *S. vulgaris*: 4.6 mg/lb of body weight daily for 5 days. Treatment should be initiated in the spring and repeated in 6 months.

(C) For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third-stage (hypobiotic), late third-stage, and fourth-stage larvae: 4.6 mg/lb of body weight daily for 5 consecutive days.

(D) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 2.3 mg/lb of body weight. Re-treatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of lungworms (*Dictyocaulus viviparus*), stomach worms (*Haemonchus contortus*, *Ostertagia ostertagi*, *Trichostrongylus axei*), and intestinal worms (*Bunostomum phlebotomum*, *Nematodirus helvetianus*, *Cooperia punctata*, *C. oncophora*, *Trichostrongylus colubriformis*, and *Oesophagostomum radiatum*).

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment.

Dated: February 28, 2007.

Steven D. Vaughn,

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

[FR Doc. E7–4204 Filed 3–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxfendazole 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 supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for over-the-counter (OTC) marketing status for oral use of oxfendazole suspension in cattle.

DATES: This rule is effective March 9, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 140–854 for SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, approved for oral use in cattle for the removal of various internal parasites. The supplemental NADA provides for OTC marketing status. The supplemental application is approved as of January 29, 2007, and the regulations are amended in 21 CFR 520.1630 to reflect the approval and a current format. 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 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(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 Parts 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. Amend § 520.1630 as follows:

■ a. Redesignate paragraph (d) as paragraph (e);

■ b. Add new paragraph (d);

■ c. Revise the introductory text in newly redesignated paragraphs (e)(1) and (e)(2); and

■ d. Revise paragraph (a) and newly redesignated paragraphs (e)(1)(i), (e)(1)(iii), (e)(2)(i), and (e)(2)(iii).

The redesignation, addition, and revisions read as follows:

§ 520.1630 Oxfendazole suspension.

(a) *Specifications*. Each milliliter of suspension contains:

(1) 90.6 milligrams (mg) oxfendazole (9.06 percent).

(2) 225.0 mg oxfendazole (22.5 percent).

* * * * *

(d) *Special considerations*. See § 500.25 of this chapter. If labeled for administration by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*. Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 10 mg per kilogram (/kg) of body weight by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks.

* * * * *

(iii) *Limitations*. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for human consumption.

(2) *Cattle*. Use the products described in paragraphs (a)(1) and (a)(2) of this section as follows:

(i) *Amount*. 4.5 mg/kg of body weight by dose syringe. Treatment may be repeated in 4 to 6 weeks.

* * * * *

(iii) *Limitations*. Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle.

Dated: February 21, 2007.

Steven D. Vaughn,

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

[FR Doc. E7–4205 Filed 3–8–07; 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; Enrofloxacin

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 Bayer HealthCare LLC. The supplemental NADA provides for changing scientific nomenclature for a bovine respiratory pathogen on labeling for enrofloxacin injectable solution.

DATES: This rule is effective March 9, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141 068 for BAYTRIL 100 (enrofloxacin) Injectable Solution used for the treatment of bovine respiratory disease associated with several bacterial pathogens. The supplemental NADA provides for changing a pathogen name from *Pasteurella haemolytica* to *Mannheimia haemolytica* on product labeling. The supplemental NADA is approved as of February 15, 2007, and the regulations in 21 CFR 522.812 are amended to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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.