Accordingly, the agency is amending the regulations in §§ 520.88b, 520.88f, 520.446, 520.447, and 522.900 to reflect the transfer of ownership.

Following these changes of sponsorship, Delmarva Laboratories, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Delmarva Laboratories, Inc.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 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 parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Delmarva Laboratories, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''059079''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.88b [Amended]

■ 4. Section 520.88b *Amoxicillin trihydrate for oral suspension* is amended in paragraph (c) by removing ''059079'' and by adding in its place ''051311''.

§ 520.88f [Amended]

■ 5. Section 520.88f *Amoxicillin trihydrate tablets* is amended in paragraph (b) by removing ''059079'' and by adding in its place ''051311''.

§ 520.446 [Amended]

■ 6. Section 520.446 *Clindamycin capsules and tablets* is amended in paragraph (b)(3) by removing ''059079'' and by adding in its place ''051311''.

§ 520.447 [Amended]

■ 7. Section 520.447 *Clindamycin liquid* is amended in paragraph (b)(2) by removing ''059079'' and by adding in its place ''051311''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.900 [Amended]

■ 9. Section 522.900 *Euthanasia solution* is amended in paragraph (b)(1) by removing ''059079'' and by adding in its place ''051311''.

Dated: September 15, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–24492 Filed 9–26–03; 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; Pyrantel Pamoate 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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of two strengths of pyrantel pamoate suspension in dogs for the management of various internal parasites.

DATES: This rule is effective September 29, 2003.

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: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–352 for PRIMEX CANINE (pyrantel pamoate) and PRIMEX CANINE–2X (pyrantel pamoate). PRIMEX CANINE contains 2.27 milligrams (mg) pyrantel base per milliliter (/mL); PRIMEX CANINE–2X contains 4.54 mg pyrantel base/mL. Both products are for oral use in dogs and puppies for the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and in dogs, puppies, and lactating bitches to prevent reinfections of *T. canis*. First Priority's PRIMEX CANINE and PRIMEX CANINE–2X are approved as generic copies of Pfizer, Inc.'s RFD Suspension and NEMEX–2 Suspension, respectively, approved under NADA 100–237. ANADA 200–352 is approved as of August 20, 2003, and the regulations are amended in § 520.2043 (21 CFR 520.2043) to reflect the approval. The basis of approval is discussed in the freedom of information summary. In addition, § 520.2043 is being amended to correct the spelling of one of the subject parasites.

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(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 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.

§ 520.2043 [Amended]

■ 2. Section 520.2043 *Pyrantel pamoate suspension* is amended in paragraph (b)(2) by numerically adding ''058829,''; and in paragraph (d)(2)(i)(B) by removing ''*Toxascarias*'' and by adding in its place ''*Toxascaris*''.

Dated: September 15, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–24493 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Copper Naphthenate Solution

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 First Priority, Inc. The ANADA provides for topical use of copper naphthenate solution on horses and ponies as an aid in treating thrush caused by organisms susceptible to copper naphthenate.

DATES: This rule is effective September 29, 2003.

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: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–304 for PRITOX, a solution of copper naphthenate for topical application on horses and ponies as an aid in treating thrush caused by organisms susceptible to copper naphthenate. First Priority's PRITOX is approved as a generic copy of Ft. Dodge Animal Health's KOPERTOX, approved under NADA 12–991. The ANADA is approved as of July 25, 2003, and 21 CFR 524.463 is amended 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 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 Part 524

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 524 is amended as follows:

PART 524–OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.463 [Amended]

■ 2. Section 524.463 *Copper naphthenate solution* is amended in paragraph (b) by removing ''*Sponsor*'' and by adding in its place ''*Sponsors*''; and by removing ''000856 and 017135'' and by adding in its place ''000856, 017135, and 058829''.

Dated: September 15, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–24495 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin and Chlortetracycline

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 Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing monensin and chlortetracycline to make two-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective September 29, 2003.

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: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200–354 for use of PENNCHLOR (chlortetracycline) and COBAN (monensin) Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler chickens. Pennfield Oil Co.'s ANADA 200–354 is approved as a generic copy of Alpharma, Inc.'s NADA 121–553 for combination use of AUREOMYCIN (chlortetracycline) and COBAN. The ANADA is approved as of August 15, 2003, and the regulations are amended in 21 CFR 558.355 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 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)(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