

**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 “*Toxascaris*” 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 KOPERTO, 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 Alpha, 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