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

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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

■ 2. Section 558.355 *Monensin* is amended in paragraph (f)(1)(xiv)*(b)* after ''046573'' by adding ''and 053389''.

Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–24436 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 26, 161, 164, and 165

[USCG–2003–14757]

RIN 1625–AA67

Automatic Identification System; Vessel Carriage Requirement

AGENCY: Coast Guard, DHS.

ACTION: Policy statement.

SUMMARY: The Coast Guard is announcing its policy and intent to establish one uniform compliance date for U.S. domestic vessels subject to Automatic Identification System carriage regulations while transiting a Vessel Traffic Service (VTS) area. On July 1, 2003, the Coast Guard published a temporary interim rule that established 3 different compliance dates, depending on particular VTS areas. This policy statement aligns these dates with the deadline date of the Maritime Transportation Security Act of 2002.

DATES: This policy is effective on September 29, 2003.

FOR FURTHER INFORMATION CONTACT: If you have questions on this Policy Statement, contact Mr. Jorge Arroyo, U.S. Coast Guard Office of Vessel Traffic Management (G–MWV), by telephone 202–267–6277, toll-free telephone 1–800–842–8740 ext. 7–6277, or electronic mail *JArroyo@comdt.uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2003, we published a temporary interim rule with request for comments and notice of public meeting titled ''Automatic Identification System; Vessel Carriage Requirement'' in the **Federal Register** (68 FR 39353). This temporary interim rule was one of a series of temporary interim rules on maritime security published in the July 1, 2003, issue of the **Federal Register**. On July 16, 2003, we published a document correcting typographical errors and omissions in that rule (68 FR 41913). The temporary interim rule established an Automatic Identification System (AIS) compliance date that varies depending upon VTS area. They are as follows:

(1) For VTS St. Marys River, not later than December 31, 2003;

(2) For VTS Berwick Bay, VMRS Los Angeles/Long Beach, VTS Lower Mississippi River, VTS Port Arthur and VTS Prince William Sound, not later than July 1, 2004; and

(3) For VTS Houston-Galveston, VTS New York, VTS Puget Sound, and VTS San Francisco, not later than December 31, 2004.

These deadline dates were established to coincide with anticipated AIS-capability at each of these respective ports via our Ports and Waterways Safety System (PAWSS) upgrades. PAWSS is an effort to establish a national transportation system that collects, processes, and disseminates information on the marine operating environment and maritime vessel traffic in major U.S. ports and waterways. Work continues on schedule in our PAWSS process; however, we recognize that having differing deadline dates has caused unwarranted confusion and may place certain vessels at a disadvantage of reaping market benefits. Therefore, the Coast Guard will amend its temporary interim rule, by a forthcoming final rule, that will adopt December 31, 2004, as the compliance date for all VTS users, not on international voyage, that are subject to the provisions of 33 CFR 164.46(b).

Policy Statement

Until the Coast Guard publishes its final rule regarding AIS carriage requirements, the following policy applies:

The Coast Guard will not enforce the deadline dates as stated in 33 CFR 164.46(c)(1) through (4).

How Long Will This Policy Remain in Effect?

This policy will remain in effect until publication of the final rule regarding AIS carriage [USCG 2003–14757], that we anticipate publishing prior to October 25, 2003. In the final rule we intend to adopt December 31, 2004, as the deadline date for domestic AIS carriage for those vessels denoted in 33 CFR 164.46(b).

Dated: September, 22 2003.

T.H. Gilmour,

Rear Admiral, Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. 03–24571 Filed 9–26–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0303; FRL–7327–3]

Dimethomorph; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dimethomorph in or on brassica, leafy greens, subgroup 5B; taro, corm; taro, leaves; and vegetable, fruiting, group 8. EPA is also deleting certain dimethomorph tolerances that are no longer needed as a result of this action. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0303, must be received on or before November 28, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division