FDC date	State	City	Airport	FDC No.	Subject
05/01/06	NY	White Plains	Westchester County	6/6586	Copter ILS/DME 162, Orig–C.
05/01/06	NY	Newburgh	Stewart Intl	6/6588	COPTER ILS 092, Orig.
05/02/06	KY	Mount Sterling	Mount Sterling-Montgomery County	6/6716	NDB RWY 21, Amdt 1B.
05/02/06	KY	Mount Sterling	Mount Sterling-Montgomery County	6/6717	GPS RWY 21, Amdt 1A.
05/02/06	KY	Hazard	Wendell H Ford	6/6718	VOR/DME RWY 14, Amdt 1.
05/02/06	KY	Covington	Cincinnati/Northern Kentucky Intl	6/6720	RNAV (GPS) RWY 36R, Orig.
05/02/06	MS	Jackson	Jackson-Evers Intl	6/6633	RNAV (GPS) RWY 16L, Orig.
05/02/06	OH	Marysville	Union County	6/6652	GPS RWY 9, Orig–A.
05/02/06	OH	Marysville	Union County	6/6654	GPS RWY 27, Orig–A.
05/03/06	OH	Freemont	Sandusky County Regional	6/6806	VOR/DME RWY 24, Orig.
05/03/06	TX	Palacios	Palacios Muni	6/6798	VOR RWY 13, Amdt 10A.

[FR Doc. 06–4472 Filed 5–30–06; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Trimethoprim and Sulfadiazine Oral 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 a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for revised food safety labeling for trimethoprim and sulfadiazine oral paste, administered to horses as a systemic antibacterial.

DATES: This rule is effective May 31, 2006.

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: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 131–918 for use of TRIBRISSEN (trimethoprim and sulfadiazine) 400 Paste, administered orally to horses as a systemic antibacterial. The supplement provides for revised food safety labeling. The supplemental NADA is approved as of April 25, 2006, and the regulations are amended in 21 CFR 520.2611 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 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.

■ 2. Revise § 520.2611 to read as follows:

§ 520.2611 Trimethoprim and sulfadiazine paste.

(a) *Specifications*. Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 000856 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) *Indications for use*. For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) *Limitations*. Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 18, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–8303 Filed 5–30–06; 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; Trimethoprim and Sulfadiazine

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 Schering-Plough Animal Health Corp. The supplemental NADA provides for

revised food safety labeling for trimethoprim and sulfadiazine injectable suspension, administered to horses as a systemic antibacterial.

DATES: This rule is effective May 31, 2006.

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: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 106–965 for use of TRIBRISSEN (trimethoprim and sulfadiazine) 48% Injection administered to horses as a systemic antibacterial. The supplement provides for revised food safety labeling. The supplemental NADA is approved as of April 26, 2006, and the regulations are amended in § 522.2610 (21 CFR 522.2610) to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that a 1997 change of sponsorship for NADA 106–965 (62 FR 61625, November 19, 1997) is not reflected in the Code of Federal Regulations. Accordingly, § 522.2610 is being revised to reflect the correct sponsor drug labeler code. This action is being taken to improve the accuracy of the regulations.

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 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. Revise § 522.2610 to read as follows:

§ 522.2610 Trimethoprim and sulfadiazine.

(a) *Specifications.* Each milliliter (mL) contains:

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors.* See Nos. 000061 and 000856 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.

(d) *Conditions of use*—(1) Dogs—(i) *Amount.* 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use.* For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to Streptococcus zooepidemicus.

(2) *Horses*—(i) *Amount.* 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

(ii) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* Not for use in horses intended for human consumption.

Dated: May 18, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–8309 Filed 5–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13–06–009]

RIN 1625–AA00

Safety Zones: Fireworks Displays in the Captain of the Port Portland Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its current regulations establishing additional safety zones on the waters of the Suislaw, Willamette, Columbia, Coos, and Chehalis Rivers, located in the Area of Responsibility (AOR) of the Captain of the Port, Portland, Oregon, during annual fireworks displays. The Captain of the Port, Portland, Oregon, is taking this action to safeguard watercraft and their occupants from safety hazards associated with these displays. Entry into these safety zones is prohibited unless authorized by the Captain of the Port.

DATES: This rule is effective June 30, 2006.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD13–06–009] and are available for inspection or copying at U.S. Coast Guard Sector Portland 6767 N. Basin Ave, Portland, OR 97217 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Charity Keuter, c/o Captain of the Port, Portland 6767 N. Basin Avenue, Portland, Oregon 97217, (503) 240–9301.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On March 28, 2006, we published a notice of proposed rule making (NPRM) entitled Safety Zone: Fireworks Displays in the Captain of the Port Portland Zone in the **Federal Register** (71 FR 15365). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Coast Guard is establishing additional permanent safety zones to allow for safe annual fireworks displays. The Coast Guard is also revising 33 CFR 165.1315 paragraph (a)(8) because the current event is no longer an event which occurs with any regularity. All