

who is accused of criminal activity receives due process of law in a criminal proceeding under the jurisdiction of the judicial branch of the Federal government.

(f) *In other circumstances.* We may disclose information to a court of competent jurisdiction in circumstances other than those stated in paragraph (e) of this section. We will make our decision regarding disclosure by balancing the needs of a court while preserving the confidentiality of information. For example, we may disclose information under a court order that restricts the use and redisclosure of the information by the participants in the proceeding; we may offer the information for inspection by the court *in camera* and under seal; or we may arrange for the court to exclude information identifying individuals from that portion of the record of the proceedings that is available to the public. We will make these determinations in accordance with § 401.140.

(g) *Other regulations on request for testimony, subpoenas and production of records in legal proceedings.* See 20 CFR part 403 of this chapter for additional rules covering disclosure of information and records governed by this part and requested in connection with legal proceedings.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 2

[Docket No. 2006N-0416]

#### Use of Ozone-Depleting Substances; Removal of Essential Use Designations; Confirmation of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of April 23, 2007, for the direct final rule that appeared in the *Federal Register* of December 7, 2006 (71 FR 70870). The direct final rule amends the regulation to remove beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, ergotamine tartrate, and ipratropium bromide, used in oral pressurized

metered-dose inhalers, from the list of essential uses of ozone-depleting substances. None of these products is currently being marketed. This document confirms the effective date of the direct final rule.

**DATES:** Effective date confirmed: April 23, 2007, except for the removal of § 2.125(e)(4)(v) (21 CFR 2.125(e)(4)(v)), which is effective August 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of December 7, 2006 (71 FR 70870), FDA solicited comments concerning the direct final rule for a 75-day period ending February 20, 2007. FDA stated that the effective date of the direct final rule would be on April 23, 2007, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period.

FDA received no significant adverse comments within the comment period. Therefore, under the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, notice is given that no objections or requests for a hearing were filed in response to the December 7, 2006, direct final rule. Accordingly, FDA is confirming that the amendment issued thereby is effective April 23, 2007, except for the removal of § 2.125(e)(4)(v), which is effective August 1, 2007.

Dated: April 17, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Diclazuril

**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 new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the veterinary prescription use of diclazuril oral pellets in horses for the treatment of equine protozoal myeloencephalitis.

**DATES:** This rule is effective April 27, 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](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed NADA 141-268 for the veterinary prescription use of PROTAZIL (1.56% diclazuril) Antiprotozoal Pellets in horses for the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*. The NADA is approved as of March 29, 2007, and the regulations in 21 CFR part 520 are amended by adding new § 520.606 to reflect the approval.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 29, 2007.

The agency has determined under 21 CFR 25.33(d)(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. Add § 520.606 to read as follows:

**§ 520.606 Diclazuril.**

(a) *Specifications.* Each 100 grams (g) of pellets contain 1.56 g diclazuril.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 1 milligram (mg) per kilogram (0.45 mg per pound) of body weight in the daily grain ration for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

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

Dated: April 13, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7-8041 Filed 4-26-07; 8:45 am]

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**DEPARTMENT OF HOMELAND  
SECURITY**

**Coast Guard**

**33 CFR Part 165**

[COTP San Francisco Bay 07-007]

RIN 1625-AA00

**Safety Zone; Kimmelman's Wedding  
Party Fireworks Display, San  
Francisco Bay, CA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone in the navigable waters of San Francisco Bay for the loading, transport, and launching of fireworks used during a wedding celebration display. This safety zone is established to ensure the safety of participants and spectators. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative.

**DATES:** This rule is effective from 1 p.m. to 9:35 p.m. on April 28, 2007.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket, are part of the docket COTP San Francisco Bay 07-007 and are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California, 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556-2950 ext. 140.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, safety zones are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

For the same reasons listed in the previous paragraph, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

**Background and Purpose**

Pyro's Spectacular Incorporated is sponsoring a brief fireworks display on April 28, 2007 in the waters of San Francisco Bay near Angel Island. The fireworks display is meant for entertainment purposes at the Kimmelman's Wedding. This safety zone is being issued to establish a temporary regulated area in San Francisco around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barge to the display location, and during the fireworks display. This safety zone around the launch barge is necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the

event sponsor a marine event permit for the fireworks display.

**Discussion of Rule**

The Coast Guard is establishing a temporary safety zone on specified waters off of San Francisco Bay near Angel Island. During the loading of the fireworks barge, while the barge is being towed to the display location, and until the start of the fireworks display, the safety zone will apply to the navigable waters around and under the fireworks barge within a radius of 100 feet. Fifteen minutes prior to and during the 5-minute fireworks display, the area to which this safety zone applies to will increase in size to encompass the navigable waters around and under the fireworks barge within a radius of 800 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 1 p.m. on April 28, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 1 p.m. and 4 p.m. on April 28, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m., the fireworks barge will be located approximately 800 feet off of Angel Island in position 37° 51'20.0" N, 122° 26'43.0" W.

The effect of the temporary safety zone will be to restrict general navigation in the vicinity of the fireworks barge while the fireworks are loaded at Pier 50, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zone. This safety zone is needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

**Regulatory Evaluation**

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public broadcast notice to mariners to ensure the safety zone will result in minimum impact. The entities most likely to be