

provides for intramuscular use of Adequan® Canine (polysulfated glycosaminoglycan) for dogs for control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of July 15, 1997, and the regulations are amended in 21 CFR 522.1850 by adding new paragraph (d) 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 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 Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, 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, this approval qualifies for 3 years of marketing exclusivity beginning July 15, 1997, because the application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1850 is amended by adding new paragraph (d) to read as follows:

§ 522.1850 Polysulfated glycosaminoglycan.

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(d) *Conditions of use—dogs—(1) Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(2) *Dosage.* 2 milligrams per pound of body weight by intramuscular injection.

(3) *Limitations.* Administer intramuscularly twice weekly for up to 4 weeks (maximum of 8 injections). Do not exceed recommended dose or regimen. Do not mix with other drugs or solvents. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 6, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD11-97-006]

RIN 2115-AE46

Special Local Regulations; Thunderboat Regatta

AGENCY: Coast Guard, DOT.

ACTION: Implementation of rule.

SUMMARY: This document implements 33 CFR 100.1101, "Southern California annual marine events, for the "World Series of Powerboat Racing" listed as "Thunderboat Regatta."

This event consists of circle races by various classes of Hydroplane racing boats and a separate but adjacent venue for dragboat racing. These regulations will be effective in an area of San Diego's Mission Bay known as Fiesta Bay, as described in Table 1 of 33 CFR 100.1101. Implementation of 33 CFR 100.1101 is necessary to control vessel traffic in the regulated areas during the event to ensure the safety of participants and spectators.

Pursuant to 33 CFR 100.1101(b)(3), Commander, Coast Guard Activities San Diego, is designated Patrol Commander for this event; he has the authority to delegate this responsibility to any

commissioned, warrant, or petty officer of the Coast Guard.

EFFECTIVE DATE: This section becomes effective at 8 a.m. PDT on September 12, 1997 and terminates at 5 p.m. PDT on September 14, 1997 unless canceled earlier by Commander, Coast Guard Activities San Diego.

FOR FURTHER INFORMATION CONTACT: QMC Michael C. Claeys, U.S. Coast Guard Activities San Diego, California; Tel: (619) 683-6309.

Discussion of Implementation. The World Series of Powerboat Racing is scheduled to occur on September 12, 13, and 14, 1997. These Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectators and participant vessels. In accordance with the regulations in 33 CFR 100.1101, no persons or vessels shall block, anchor, or loiter in the regulated area; nor shall any person or vessel transit through the regulated area, or otherwise impede the transit of participant or official patrol vessels in the regulated area, unless authorized by the Patrol Commander.

Dated: August 8, 1997.

J.M. MacDonald,

Captain, U.S. Coast Guard, Commander, Eleventh Coast Guard District Acting.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01-97-083]

RIN 2115-AE46

Special Local Regulation: Fireworks Displays Within the First Coast Guard District

AGENCY: Coast Guard, DOT.

ACTION: Implementation of rule.

SUMMARY: This document provides notice of the dates and times of the special local regulations contained in 33 CFR 100.114, Fireworks Displays within the First Coast Guard District. All vessels will be restricted from entering the area of navigable water within a 500 yard radius of the fireworks launch platform for each event listed in the table below. Implementation of these regulations is necessary to control vessel traffic within the regulated area to ensure the safety of spectators.

EFFECTIVE DATE: The regulations in 33 CFR 100.114 are effective from one hour before the scheduled start of the event until thirty minutes after the last