

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.

\* \* \* \* \*

(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.*

[FR Doc. 97-22623 Filed 8-25-97; 8:45 am]

BILLING CODE 4160-01-F

## 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.*

[FR Doc. 97-22671 Filed 8-25-97; 8:45 am]

BILLING CODE 4910-14-M

## 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

firework is exploded for each event listed in the table below. The events are listed in the table below. The events are listed chronologically by month with their corresponding number listed in the special local regulation, 33 CFR 100.114.

**ADDRESSES:** Comments should be mailed to Commander (osr), First Coast Guard District, Captain John Foster Williams Federal Building, 408 Atlantic Ave., Boston, MA 02110-3350, or may be hand delivered to Room 734 at the same address, between 8 a.m. and 4 p.m., Monday through Friday, except federal holidays. Comments will become part of this docket and will be available for inspection or copying at the above address.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander William H. Rypka, Office of Search and Rescue branch, First Coast Guard District at (617) 223-8460.

**SUPPLEMENTARY INFORMATION:** This document implements the special local regulations in 33 CFR 100.114 (62 FR 30988; June 6, 1997). All vessels are prohibited from entering a 500 yard radius of navigable water surrounding the launch platform used in each fireworks displayed listed below.

#### Table 1—Fireworks Displays

##### August

2. Summer Music Fireworks  
Date: August 23, 1997  
Time: 9:00 p.m. to 10:30 p.m.  
Location: Niantic River, Harkness Park, Waterford, CT  
Lat: 41 18.2N, Long: 072 06.5W (NAD 1983)
4. Fall River Celebrates America Fireworks  
Date: August 9, 1997  
Time: 9:00 p.m. to 10:00 p.m.  
Location: Taunton River, Vicinity of buoy #17, Fall River, MA  
Lat: 41-33N Long: 071-10W (NAD 1983)
6. Oaks Bluff Fireworks  
Date: August 22, 1997  
Time: 4:00 p.m. to 10:00 p.m.  
Location: Oaks Bluff Beach, Oaks Bluff, MA  
Lat: 41-27N Long: 070-33W (NAD 1983)
8. Gloucester Fireworks  
Date: August 30, 1997  
Rain Date: August 30, 1997  
Time: 8:00 p.m. to 11:00 p.m.  
Location: Gloucester Harbor, Gloucester, MA  
Lat: 42 36"18"N Long: 070 40"34"W (NAD 1983)  
Including the Northwest Shoreline of Ten Pound Island.
9. Salute to Summer  
Date: August 29, 1997  
Time: 9:00 p.m. to 10:00 p.m.

Location: Narragansett Bay, East Passage, off Coasters Harbor Island, Newport, RI

Lat: 41-30N Long: 071-20W (NAD 1983)

#### 10. Norwich Harbor Day Fireworks

Date: August 31, 1997

Time: 8:45 p.m. to 11:00 p.m.

Location: Norwich Harbor, off American Wharf Marina, Norwich, CT

Lat: 41-31.22N Long: 72-04.50W (NAD 1983)

Dated: August 8, 1997.

**R.M. Larrabee,**

*Rear Admiral, U.S. Coast Guard Commander, First Coast Guard District.*

[FR Doc. 97-22672 Filed 8-25-97; 8:45 am]

BILLING CODE 4910-14-M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 117

[CGD05-97-002]

RIN 2115-AE47

#### Drawbridge Operation Regulations; Ship Channel, Great Egg Harbor Bay, New Jersey

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** At the request of the New Jersey Department of Transportation (NJDOT), the Coast Guard is changing the regulations governing operation of the Route 52 (Ship Channel) Bridge across Great Egg Harbor Bay, mile 0.5, between Somers Point and Ocean City, New Jersey.

This rule will require the Route 52 (Ship Channel) Bridge to open on signal except that, between Memorial Day and Labor Day from 8 a.m. to 8 p.m., the draw need only open on the hour and half hour. During the summer tourist season, this rule will curtail delays to vehicular traffic while still providing for the reasonable needs of navigation.

**DATES:** This final rule is effective on September 25, 1997.

**ADDRESSES:** Documents as indicated in this preamble are available for inspection or copying at the office of the Commander (Aowb), USCG Atlantic Area, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6222.

#### FOR FURTHER INFORMATION CONTACT:

Ann Deaton, Bridge Administrator, USCG Atlantic Area, (757) 398-6222.

## SUPPLEMENTARY INFORMATION:

### Regulatory History

On April 21, 1997, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) entitled "Drawbridge Operation Regulations; Ship Channel, Great Egg Harbor Bay, New Jersey" in the **Federal Register** (62 FR 19243). The Coast Guard received one letter commenting on the proposed rulemaking. No public hearing was requested and none was held.

### Background and Purpose

The current regulations found at 33 CFR 117.753 require the Route 52 (Ship Channel) bridge to open on signal except that from 11 p.m. to 7 a.m., year-round a 24 hour advance notice is required; and from Memorial Day through Labor Day from 10 a.m. to 8 p.m. on Saturdays, Sundays, and Federal holidays, the bridge opens only on the hour and half hour for recreational vessels.

The New Jersey Department of Transportation (NJDOT) requested that 33 CFR 117.753 be amended to extend the periods during the summer months in which the bridge must open only on the hour and half hour. In support of its request NJDOT contended that its records show that requests for openings from Memorial Day through Labor Day are minimal in number, such that the requested amendment would not significantly affect vessel traffic.

The Coast Guard reviewed NJDOT's bridge logs for 1993 through 1995, copies of which are included in the docket of this rulemaking. According to the logs, for the years 1993 through 1995, from May through September between 8 a.m. and 8 p.m. Monday through Friday, the Route 52 (Ship Channel) bridge opened 250, 248, and 287 times, respectively, for recreational and commercial vessels, an average of 12 openings per week. The Coast Guard believes that this rule will balance the needs of vehicular and vessel traffic without unduly restricting vessel navigation.

NJDOT also requested a change to the operating regulations for the Route 52 (Beach Thorofare) Bridge. Due to the close proximity of the Route 52 bridges over Beach Thorofare and Ship Channel, which are located approximately two miles apart, synchronized openings will augment the effectiveness of the recommended change to the regulations for the Route 52 (Ship Channel) Bridge.

Therefore, the Coast Guard is amending Section 117.753 by revising