

## SUPPLEMENTARY INFORMATION:

**Background**

On June 4, 1997, Customs published in the **Federal Register** (62 FR 30448) interim regulations (T.D. 97-45) which amended § 24.24 of the Customs Regulations (19 CFR 24.24) to update the list of ports that process commercial vessels that transport cargo that are subject to the Water Resources Development Act of 1986. That document contained several typographical errors in the columns headed "Port code, port name and state" and "Port descriptions and notations", both of which may be relied on by importers in the preparation of necessary entry documentation. The errors identified are under the headings for Delaware, the District of Columbia, Illinois, Massachusetts, and Michigan, and consist of incomplete State abbreviations (for Maryland and Illinois), incorrect port codes (for East Chicago and Escanaba), and incomplete port descriptions (for Delaware and Massachusetts). Accordingly, this document corrects those typographical errors.

**Corrections to Publication**

The document (FR Doc. 97-14409) published in the **Federal Register** (62 FR 30448) on June 4, 1997, is corrected as follows:

1. On page 30450, under the heading for "Delaware", in the column headed "Port descriptions and notations", in the second line the word "lower" is added after the words "all points on the";

2. Also on page 30450, under the heading for "District of Columbia", in the column headed "Port code, port name and state", in the first line the capital letter "D" is removed and the designation "MD" is added in its place;

3. On page 30451, under the heading for "Illinois", in the column headed "Port code, port name and state", in the third line the numbers "3902" are removed and the numbers "3904" are added in their place; and in the column headed "Port descriptions and notations", in the first line the designation "IL" is removed and the designation "IL" is added in its place;

4. Also on page 30451, under the heading for "Massachusetts", in the column headed "Port descriptions and notations", in the second line the word "River" is removed and the word "Rivers" is added in its place; and

5. On page 30452, under the heading for "Michigan", in the column headed "Port code, port name and state", in the fifth line the number "3803" is removed

and the number "3808" is added in their place.

Dated: August 21, 1997.

**Harold M. Singer,**

*Chief, Regulations Branch.*

[FR Doc. 97-22639 Filed 8-25-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin Injection; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations for gentamicin injection. A document which published in the **Federal Register** of May 15, 1996 (61 FR 24440), inadvertently resulted in the 1997 edition of the Code of Federal Regulations not containing reference to two gentamicin injection approvals. This document amends the gentamicin injection regulations to reflect the approvals.

**EFFECTIVE DATE:** August 26, 1997.

**FOR FURTHER INFORMATION CONTACT:** David L. Gordon, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1739.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 15, 1996 (61 FR 24440), FDA published a document to reflect approval of Schering-Plough's supplemental NADA 101-862. In amending the regulations to reflect the supplemental approval, FDA provided amendatory instructions which resulted in two paragraphs inadvertently being removed. This document reestablishes those paragraphs in 21 CFR 522.1044(b)(3) and (b)(4).

**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 522.1044 is amended by adding paragraphs (b)(3) and (b)(4) to read as follows:

**§ 522.1044 Gentamicin sulfate injection.**

\* \* \* \* \*

(b) \* \* \*

(3) See No. 054273 for use of 50 milligrams-per-milliliter solution in dogs as in paragraph (d)(5) of this section.

(4) See No. 050604 for use of 100 milligrams-per-milliliter solution in chickens as in paragraph (d)(3) of this section.

\* \* \* \* \*

Dated: August 18, 1997.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 97-22622 Filed 8-25-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Polysulfated Glycosaminoglycan**

**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 Luitpold Pharmaceuticals, Inc. The NADA provides for intramuscular injection of polysulfated glycosaminoglycan for dogs for control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

**EFFECTIVE DATE:** August 26, 1997.

**FOR FURTHER INFORMATION CONTACT:** Ellen M. Buck, Center For Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

**SUPPLEMENTARY INFORMATION:** Luitpold Pharmaceuticals, Inc., Animal Health Division, 1 Luitpold Dr., Shirley, NY 11967, filed NADA 141-038 that

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]

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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.*

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

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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