

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 § 522.1192 to read as follows:

§ 522.1192 Ivermectin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(C), (e)(2)(iii), (e)(3), (e)(4) and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 059130 and 055529 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(B), (e)(2)(iii), (e)(3), (e)(4), and (e)(5) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Labeling shall bear the following precaution: “This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.”

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms per kilogram (µg/kg) of body weight by intramuscular injection.

(ii) *Indications for use*. For the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *S. edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage

larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (microfilariae) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *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.

(2) *Cattle*—(i) *Amount*. 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use*—(A) For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *T. axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (scabies) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*).

(B) For control of infections of *D. viviparus* for 28 days after treatment, and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

(C) For control of infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations*. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) *Swine*—(i) *Amount*. 300 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostromylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *S. ransomi* (somatic larvae)); lungworms (*Metastrongylus*

spp. (adults only)); lice (*H. suis*); and mites (*S. scabiei* var. *suis*).

(iii) *Limitations*. Do not treat swine within 18 days of slaughter.

(4) *American bison*—(i) *Amount*. 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of grubs (*H. bovis*).

(iii) *Limitations*. Do not slaughter within 56 days of last treatment.

(5) *Reindeer*—(i) *Amount*. 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations*. Do not treat reindeer within 56 days of slaughter.

(6) *Ranch-raised foxes*—(i) *Amount*. 200 µg/kg of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) *Indications for use*. For treatment and control of ear mites (*Otodectes cynotis*).

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[CGD13-07-013]

RIN 1625-AA00

Special local regulation: ULHRA Hydroplane Races, Howard Amon Park, Richland, WA

AGENCY: Coast Guard, DHS.

ACTION: Special local regulation temporary final rule.

SUMMARY: The Coast Guard is undertaking two actions with regard to the above captioned regulation. The first is to withdraw the temporary final rule previously published on April 23, 2007 because it erroneously described the race area. The second is to correct the previous error by establishing a temporary special local regulation for the ULHRA National Series Hydroplane Race to be held on the waters of the Columbia River in the vicinity of Howard Amon Park, Richland, WA. These special local regulations limit the movement of non-participating vessels in the regulated race area. This

temporary rule is needed to provide for the safety of life on navigable waters during the event.

DATES: This regulation is effective from 7 a.m. (PDT) to 7 p.m. (PDT) on May 19 and 20, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket (CGD13-07-013) and are available for inspection or copying at U. S. Coast Guard Sector Portland, 6767 N. Basin Avenue, Portland, Oregon 97217 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Petty Officer Michelle Duty, c/o Captain of the Port, Portland 6767 N. Basin Avenue, Portland, Oregon 97217, (503) 240-2590.

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) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing an NPRM would be contrary to public interest since immediate action is necessary to ensure the safety of vessels and spectators. If normal notice and comment procedures were followed, or if the effective date of this rule were delayed by 30 days, this rule would not become effective until after the date of the event. For this reason, following normal rulemaking procedures in this case would be contrary to the public interest.

Background and Purpose

The Coast Guard is undertaking two actions in this document. The first is to withdraw the temporary final rule previously published on April 23, 2007 at 72 FR 20047 because it erroneously described the race area. The second is to correct the previous error by establishing a temporary special local regulation for the ULHRA National Series Hydroplane Race to be held on the waters of the Columbia River in the vicinity of Howard Amon Park, Richland, WA.

The Coast Guard is establishing a temporary special local regulation to allow for a safe racing event. This event occurs on the Columbia River in the vicinity of Howard Amon Park in Richland, WA and is scheduled to start at 7 a.m. (PDT) and last until 7 p.m. (PDT) on May 19 and 20, 2007. This event may result in a number of recreational vessels congregating near

the hydroplane races. The hydroplane race poses several dangers to the public including excessive noise, objects falling from any accidents, and hydroplanes racing at high speeds in proximity to other vessels. Accordingly, the Special local regulation is needed to protect watercraft and their occupants from safety hazards associated with the event. This Special local regulation will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other federal, state, and local agencies.

Discussion of Rule

This temporary rule will create a regulated area to assist in minimizing the inherent dangers associated with hydroplane races. These dangers include, but are not limited to, excessive noise, race craft traveling at high speed in close proximity to one another and to spectator craft, and the risk of airborne objects from any accidents associated with hydroplanes. In the event that hydroplanes require emergency assistance, rescuers must have immediate and unencumbered access to the craft. The Coast Guard, through this action, intends to promote the safety of personnel, vessels, and facilities in the area. Due to these concerns, public safety requires these regulations to provide for the safety of life on the navigable waters.

Regulatory Evaluation

This temporary 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. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this temporary rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. This expectation is based on the fact that the regulated area established by this rule encompasses an area on the Columbia River near Howard Amon Park in Richland, WA not frequented by commercial navigation. The regulation is established for the benefit and safety of the recreational boating public and the event will pause in order to allow the ferry to pass through the area at its allotted times, any negative recreational boating impact is offset by the benefits

of allowing the hydroplanes to race. This rule would be enforced from 7 a.m. to 7 p.m. Pacific Daylight Time each day on May 19 and 20, 2007. For the above reasons, the Coast Guard does not anticipate any significant economic impact.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Columbia River during the time mentioned under *Background and Purpose*. This Special local regulation will not have a significant economic impact on a substantial number of small entities due to its short duration and small area. The only vessels likely to be impacted will be recreational boaters, small passenger vessel operators, and a ferry that runs through the regulated area twice a day. The event is held for the benefit and entertainment of the recreational and small passenger vessel operators, and the event will pause in order to allow the ferry to pass through the area at its allotted times. Because the impacts of this proposal are expected to be so minimal, the Coast Guard certifies under 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this temporary rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this temporary rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offered to assist small entities in understanding the rule so that they can

better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-888-REG-888-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that order and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a state, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian tribal governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D

and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(h) of Commandant Instruction M16475.1D, from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine event permit are specifically excluded from further analysis and documentation under that section.

Under figure 2-1, paragraph (34)(h) of the instruction, an "Environmental Analysis Check List" and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and Recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

§ 100.T13-009 [Withdrawn].

■ 2. Withdraw temporary § 100.T13-009.

■ 3. Add temporary § 100.T13-010 to read as follows:

§ 100.T13-010 ULHRA Hydroplane Races Howard Amon Park, Richland, Washington.

(a) Regulated Area. The regulated area is defined as the waters of the Columbia River from bank to bank in the vicinity of Howard Amon Park on the Columbia River in Richland, Washington commencing at the Interstate 182 Bridge and continuing up river Northward 3.0 miles and terminating at the Columbia River Mile 339.

(b) Special Local Regulations. This event will take place from 7 a.m. PDT to approximately 7 p.m. PDT May 19 to 20, 2007, in the described waters of the Columbia River in Richland, Washington.

(1) No persons may enter or remain in the regulated area except for participants in the event, supporting personnel, vessels registered with the event organizer, and personnel or

vessels authorized by the Coast Guard Patrol Commander.

(2) The Coast Guard Patrol Commander is a commissioned, warrant, petty officer, or auxiliariest of the Coast Guard who has been designated by Commander, Coast Guard Sector Portland. A Coast Guard Auxiliariest, when so appointed by the COTP per 14 U.S.C 831, may act as the Patrol Commander. The Patrol Commander is empowered to control movement of vessels in the regulated area and adjoining waters during the hours these regulations are in effect.

(3) A succession of sharp, short signals by whistle, siren, or horn from vessels patrolling the area shall serve as a signal to stop. Vessels or persons signaled shall stop and shall comply with the orders of the patrol vessels. Failure to due so may result in the expulsion from the area, citation, for failure to comply or both.

(4) Any spectator vessel may anchor outside the regulated area specified in paragraph (a) of this section, but may not block a navigable channel.

Dated: May 4, 2007.

K.S. Cook,

Captain, U.S. Coast Guard, Acting Commander, 13th Coast Guard District.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[USCG-2007-28201]

RIN 1625-ZA13

Vessels Carrying Oil, Noxious Liquid Substances, Garbage, Municipal or Commercial Waste, and Ballast Water; Technical, Organizational and Conforming Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This rule makes a non-substantive change to Title 33 of the Code of Federal Regulations. The purpose of this rule is to make a conforming amendment and technical correction to a Coast Guard navigation and navigable water regulation. This rule will have no substantive effect on the regulated public.

DATES: This final rule is effective May 17, 2007.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble

as being available in the docket, are part of docket USCG-2007-28201 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Ray Davis, Coast Guard, telephone 202-372-1461. If you have questions on viewing the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202-493-0402.

SUPPLEMENTARY INFORMATION:

Regulatory History

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under both 5 U.S.C. 553(b)(A) and (b)(B), the Coast Guard finds this rule is exempt from notice and comment rulemaking requirements because this change involves agency organization and practices, and good cause exists for not publishing an NPRM for the revision in the rule because it is a non-substantive change. This rule consists only of a technical and conforming amendment. The change will have no substantive effect on the public; therefore, it is unnecessary to publish an NPRM. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

This rule, which becomes effective May 17, 2007, makes a technical correction to 33 CFR part 151. This rule does not create any substantive requirements.

Discussion of Rule

This rule corrects the authority citation in part 151 and amends 33 CFR § 151.2010. When the Coast Guard converted the voluntary ballast water management guidelines in 33 CFR part 151, Subpart D, into a mandatory ballast water management program (69 FR 44952, July 28, 2004), we inadvertently did not make changes to § 151.2010 to reflect several exemptions. Specifically, that crude oil tankers engaged in coastwise trade and Department of Defense and Coast Guard vessels were exempted from the mandatory ballast water management requirements in § 151.2035, which had previously been a voluntary program as stated by

statutory language in the National Invasive Species Act of 1996 (NISA). We discussed this exemption and its reasoning in the preamble of the 2004 final rule, stating, "NISA authorizes specific exemptions for crude oil tankers engaged in coastwise trade, and Department of Defense and Coast Guard vessels. Therefore, we do not currently have the authority to include these vessels in the applicability for the final rule." This statement made clear our intention to carry that exemption forward into the mandatory program.

With respect to the exemptions for vessels operating exclusively within one Captain of the Port (COTP) Zone, the language changed to include only exemptions for §§ 151.2040 and 151.2045, but not § 151.2035. This exemption is not taken from NISA. The Coast Guard established it as a discretionary exercise of its regulatory authority after notice and comment rulemaking. It would be inappropriate to expand the ballast water management requirements exemption beyond those previously granted by means of a technical amendment not subject to a notice and comment rulemaking. These vessels will continue following the requirements in § 151.2035. While this includes the requirements in § 151.2035(b), which calls for ballast water management for vessels operating outside the U.S. EEZ, vessels operating exclusively in a COTP Zone will not operate outside the U.S. EEZ and, therefore, compliance with those particular requirements is not mandatory. These vessels are reminded, however, that they must comply with § 151.2035(a), which calls for ballast water management inside of U.S. waters.

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. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. As this rule involves internal agency practices and procedures and a non-substantive change, it will not impose any costs on the public.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities.