PART 529—CERTAIN OTHER DOSAGE FORMS NEW ANIMAL DRUGS

21. The authority citation for 21 CFR part 529 continues to read as follows:


§529.50 [Redesignated as §529.56 and Amended]

22. Redesignate §529.50 as §529.56 and revise it to read as follows:

§529.56 Amikacin.

(a) Specifications. Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) Sponsors. See Nos. 000856 and 059130 in §510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount. Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) Indications for use. For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including Escherichia coli, Pseudomonas spp., and Klebsiella spp.

(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.

23. In §529.1030, revise paragraphs (d)(1)(i) and (d)(1)(iv) to read as follows:

§529.1030 Formalin.

* * * * *

(d) * *

(1) * *

(i) Select finfish. For control of external protozoa Ichthyophthirius spp., Chilodonella spp., Ichthyobodo spp., Ambiphrya spp., Epistyli spp., and Trichodina spp., and monogenetic trematodes Cleidodiscus spp., Gyrodactylus spp., and Dactylogyrus spp., on salmon, trout, catfish, largemouth bass, and bluegill. * * * * *

(iv) All finfish. For control of external protozoa Ichthyophthirius spp., Chilodonella spp., Ichthyobodo spp., Ambiphrya spp., Epistyli spp., and Trichodina spp., and monogenetic trematodes Cleidodiscus spp., Gyrodactylus spp., and Dactylogyrus spp.

* * * * *


Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2009–0996]

RIN 1625–AA08

Special Local Regulation; Hydroplane Races Within the Captain of the Port Puget Sound Area of Responsibility

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a special local regulation to restrict vessel movement in designated permanent hydroplane race areas in Dyes Inlet, Lake Washington and Lake Sammamish, WA during permitted hydroplane race events. When this special local regulation is activated, and thus subject to enforcement, this rule will limit the movement of non-participating vessels within the regulated race areas immediately prior to, during and immediately following the conclusion of permitted hydroplane marine events. This rule is needed to provide effective control over these events while ensuring the safety of the maritime public.

DATES: This rule is effective March 29, 2011.

ADDRESS: 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–2009–0996 and are available online by going to www.regulations.gov, inserting USCG–2009–0996 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail LTJG Ashley M. Wanzer, Waterways Management, Sector Puget Sound, Coast Guard; telephone 206–217–6175, e-mail SectorPugetSoundWWM@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On Tuesday, January 19, 2010, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone Regulation; Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility in the Federal Register (75 FR 2833). On Wednesday, January 19, 2011, we published a supplemental notice of proposed rulemaking (SNPRM), revising the rulemaking to create a special local regulation designating three permanent hydroplane race areas under 33 CFR part 100 in the Federal Register (76 FR 3057). We did not receive any comments on the NPRM or SNPRM and did not receive any requests for a public meeting. A public meeting was not held.

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. Immediate action is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the intended objective of promoting safety during these permitted events because the ULHRA Spring Training takes place on 21 April 2011 in the Lake Washington designated race area and this is less than 30 days after publication in the Federal Register.

Basis and Purpose

The U.S. Coast Guard is establishing special local regulations to establish three permanent designated hydroplane race areas in Dyes Inlet, Lake Washington, and Lake Sammamish, WA within the Captain of the Port, Puget Sound Area of Responsibility. This action is necessary in order to restrict vessel movement in the vicinity of the race courses thereby promoting safety on navigable waters during these events.

Background

The Coast Guard receives numerous marine event permits for hydroplane races taking place on the waterways of Dyes Inlet, Lake Washington, and Lake Sammamish, WA. This rule establishes a special local regulation to restrict vessel movement in designated hydroplane race areas during permitted hydroplane marine events. This rule enables event sponsors and the Coast Guard to adequately provide safety in support of these marine events.

Initial Enforcement

The Coast Guard will enforce the special local regulation for Lake Washington in 33 CFR 100.1308 from 10 a.m. until 4 p.m. on April 21, 2011.
Discussion of Comments and Changes
The notice of proposed rulemaking and supplemental notice of proposed rulemaking for this rule did not receive any comments.

Regulatory Analyses
We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review
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.

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 small entities: The owners or operators of vessels intending to transit or anchor within these designated hydroplane race areas while enforced on the waters of northern Dyes Inlet, Lake Washington, and Lake Sammamish, Washington. This proposed rule will not have a significant economic impact on a substantial number of small entities because it is small in size and short in duration. The only vessels likely to be impacted will be recreational boaters.

Assistance for Small Entities
Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could 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–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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 it does not have implications for federalism.

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 (adjusted for inflation) 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 cause a 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 create 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 Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, 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 this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves a special local regulation to establish vessel movement restrictions in designated race areas immediately prior to, during and immediately following permitted hydroplane race events. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

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

PART 100—REGATTAS AND MARINE PARADES

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

Authority: 33 U.S.C. 1233.

2. Add § 100.1308 to read as follows:

§ 100.1308 Special Local Regulation; Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility.

(a) Location. The following areas are designated race areas for the purpose of reoccurring hydroplane races:

(1) Dyes Inlet, West of Port Orchard, WA to include all waters north to land from a line connecting the following points 47°37.36′ N, 122°42.29′ W and 47°37.74′ N, 122°40.64′ W (NAD 1983).

(2) Lake Washington. South of the Interstate 90 bridge and north of Andrew’s Bay to include all waters east of the shoreline within the following points: 47°34.15′ N, 122°16.40′ W; 47°34.31′ N, 122°15.96′ W; 47°35.18′ N, 122°16.31′ W; 47°35.00′ N, 122°16.71′ W (NAD 1983).

(3) Lake Sammamish. South to land from a line connecting the following points 47°33.810′ N, 122°04.810′ W and 47°33.810′ N, 122°03.674′ W (NAD 1983).

(b) Notice of enforcement or suspension of enforcement. This special local regulation will provide notice to the Coast Guard and may include but are not limited to, Broadcast Notice to Mariners or Local Notice to Mariners.

(c) Regulations. (1) When this special local regulation is enforced, non-participant vessels are prohibited from entering the designated race areas unless authorized by the designated on-scene Patrol Commander. Spectator craft may remain in designated spectator areas but must follow the directions of the designated on-scene Patrol Commander. The event sponsor may also function as the designated on-scene Patrol Commander. The event sponsor will provide notice to all persons entering or moving within the spectator area must operate at speeds which will create a minimum wake.

(2) Emergency signaling. A succession of sharp, short signals by whistle or horn from vessels patrolling the areas under the discretion of the designated on-scene Patrol Commander shall serve as a signal to stop. Vessels signaled shall stop and shall comply with the orders of the patrol vessel. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.


A.T. Ewell,
Captain, U.S. Coast Guard, Acting District Commander, Thirteenth Coast Guard District.

SUMMARY: This correction is effective March 29, 2011.

FOR FURTHER INFORMATION CONTACT: Idaho Roadless Coordinator Joan Dickerson at 406–329–3314. Additional information concerning these administrative corrections, including the corrected maps, may be obtained on the Internet at http://roadless.fs.fed.us. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Idaho Roadless Rule authorizes administrative corrections to the maps of lands identified in 36 CFR 294.22(c), including but not limited to, adjustment or correction clerical errors, typographical errors, mapping errors, or improvements in mapping technology. The Chief may issue administrative corrections after a 30-day public notice and opportunity to comment.

The Agency presented the corrections to the Idaho Roadless Rule Advisory Commission on September 28, 2010. The Commission recommended to the Governor of Idaho that the corrections be made and that the Agency contact the Valley County Commissioners. The Valley County Commissioners supported the corrections.

The Agency requested comment and/ or met with the Shoshone-Paiute Tribes of Duck Valley, the Shoshone-Bannock Tribes of Fort Hall, and the Nez Perce Tribe. No comments or concerns from the Tribes were received.

Consideration of Comments

The Chief provided a 30-day public notice and opportunity to comment (75 FR 54542). A total of 13 comments were received from 9 individuals.

Two respondents were concerned about the original classification of lands in the Big Creek Fringe, Placer Creek, Secesh and Smith Creek Idaho Roadless Areas on the Payette National Forest. These corrections remedy clerical errors relating to regulatory classifications involving two Forest Plan Special Areas (Big Creek and French Creek) and a mapping error. These corrections are made pursuant to 36 CFR 294.27(a).

DATES: This correction is effective March 29, 2011.

AGENCY: Forest Service, USDA.

ACTION: Final administrative correction.

SUMMARY: The Forest Service, U.S. Department of Agriculture (USDA), is issuing administrative corrections affecting Big Creek Fringe, French Creek, Placer Creek, Secesh, and Smith Creek Idaho Roadless Areas on the Payette National Forest. These corrections remedy clerical errors relating to regulatory classifications involving two Forest Plan Special Areas (Big Creek and French Creek) and a mapping error. These corrections are made pursuant to 36 CFR 294.27(a).