

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-391 for Griseofulvin Powder, ANADAs 200-146 and 200-247 for Oxytetracycline Hydrochloride Soluble Powder, and ANADAs 200-313 and 200-386 for Levamisole Hydrochloride Soluble Pig Wormer and Drench Powder to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. Accordingly, the agency is amending the regulations in part 520 (21 CFR part 520) to reflect the transfer of ownership and a current format.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1100 [Amended]

■ 2. In paragraph (b)(2) of § 520.1100, remove “059130” and in its place add “061623”.

■ 3. In § 520.1242, revise the section heading to read as follows:

§ 520.1242 Levamisole.

■ 4. In § 520.1242a, revise the section heading to read as set forth below, and in paragraph (b)(4) remove “059130” and in its place add “061623”.

§ 520.1242a Levamisole powder.

* * * * *

§ 520.1660d [Amended]

■ 5. In § 520.1660d, in paragraphs (b)(5), (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove “059130” and in its place add “061623”.

Dated: May 7, 2012.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2012-11382 Filed 5-11-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG-2011-1172]

RIN 1625-AA00

Safety Zone; America’s Cup World Series, East Passage, Narragansett Bay, RI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones in the navigable waters of the East Passage, Narragansett Bay, Rhode Island, during the America’s Cup World Series (ACWS) sailing vessel racing event.

DATES: This rule is effective June 13, 2012 until 5:00 p.m. on July 1, 2012.

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-2011-1172 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-1172 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 email Mr. Edward G. LeBlanc, Waterways Management Division at Coast Guard Sector Southeastern New England, telephone 401-435-2351, email Edward.G.LeBlanc@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

On February 10, 2012, we published a notice of proposed rulemaking

(NPRM) entitled “Safety Zones; America’s Cup World Series, East Passage, Narragansett Bay, RI” in the **Federal Register** (77 FR 7025). We received one comment on the proposed rule.

Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; Public Law 107-295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety zones.

This rule is necessary to provide for the safety of life and navigation for both participants and spectators involved with the America’s Cup World Series in the vicinity of Newport, RI.

Discussion of Comments and Changes

One comment was received, supporting this rule. The commenter believed the safety zones established by this rule will improve navigation safety for all mariners and facilitate a safe America’s Cup World Series event. No changes were made to the language contained in the NPRM.

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.

Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, 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 minimal. Although this regulation may have some impact on the public, the potential impact will be minimized for the following reasons: Vessels will only be restricted from the East Passage of Narragansett Bay by the designated safety zone for a maximum of six hours per day for a maximum of 10 days; there is an alternate route, the West Passage of Narragansett Bay, that does not add substantial transit time, is already routinely used by mariners, and will not be affected by these safety zones; many vessels, especially all recreational vessels, may transit in all

portions of the affected waterway except for those areas covered by the safety zones; and vessels may enter or pass through the affected waterway with the permission of the Captain of the Port (COTP) or the COTP's representative.

Notifications of the ACWS and associated safety zones will be made to mariners through the Rhode Island Port Safety Forum, local Notice to Mariners, event sponsors, and local media well in advance of the event.

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 would not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which might be small entities: Owners or operators of vessels intending to transit, fish, or anchor in the East Passage of Narragansett Bay, Rhode Island, during the ACWS races.

The rule will not have a significant economic impact on a substantial number of small entities for the following reasons: Vessels will only be restricted from the designated safety zone for a maximum of six hours per day for a maximum of 10 days; vessels may transit in all portions of the affected waterway except for those areas covered by the safety zones, and vessels may enter or pass through the affected waterway with the permission of the COTP or the COTP's representative.

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 this 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–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 would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule would 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 would not create an environmental risk to health or risk to safety that might 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 would 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) 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. Any comments made in response to the previously published Notice of Proposed Rulemaking for this

action were also considered in arriving at this conclusion. This rule is categorically excluded, under figure 2–1, paragraphs (34)(g) and (34)(h) of the Instruction since it involves establishment of safety zones for marine related 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 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new § 165.T1172 to read as follows:

§ 165.T1172 Safety Zones; America's Cup World Series, East Passage, Narragansett Bay, Rhode Island.

(a) *Location.* The following areas are safety zones:

(1) Safety zone “North”, an area bounded by the following coordinates:

- (i) 41–29.806N, 071–21.504W
- (ii) 41–30.049N, 071–20.908W
- (iii) 41–28.883N, 071–19.952W
- (iv) 41–28.615N, 071–19.952W

(2) Safety zone “South”, an area bounded by the following coordinates:

- (i) 41–28.432N, 071–21.628W
- (ii) 41–28.898W, 071–20.892W
- (iii) 41–29.992W, 071–21.013W
- (iv) 41–29.287N, 071–20.406W
- (v) 41–28.894N, 071–19.958W
- (vi) 41–28.085N, 071–21.211W

(b) *Enforcement Period.* Vessels will be prohibited from entering these safety zones during the America's Cup World Series (ACWS) sailing vessel racing events between 11 a.m. and 5 p.m. each day from Friday, June 22, 2012 to Sunday, July 1, 2012.

(c) *Definitions.* The following definitions apply to this section:

(1) *Designated Representative.* A “designated representative” is any Coast Guard commissioned, warrant or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port, Sector Southeastern New England (COTP), to act on his or her behalf. The

designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF–FM radio or loudhailer. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(2) *Official Patrol Vessels.* Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP.

(3) *Patrol Commander.* The Coast Guard may patrol each safety zone under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM.”

(4) *Spectators.* All persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 as well as the following regulations apply to the safety zones established in conjunction with the America's Cup World Series, East Passage, Narragansett Bay, Newport, RI. These regulations may be enforced for the duration of the event.

(2) No later than 10 a.m. each day of the event, the Coast Guard will announce via Safety Marine Information Broadcasts and local media which of the safety zones, either “North” or “South”, will be enforced for that day's America's Cup World Series races.

(3) Vessels may not transit through or within the safety zones during periods of enforcement without Patrol Commander approval. Vessels permitted to transit must operate at a no-wake speed, in a manner which will not endanger participants or other crafts in the event.

(4) Spectators or other vessels shall not anchor, block, loiter, or impede the movement of event participants or official patrol vessels in the safety zones unless authorized by an official patrol vessel.

(5) The Patrol Commander may control the movement of all vessels in the safety zones. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the lawful directions issued. Failure to comply with a lawful direction may result in expulsion from the area, citation for failure to comply, or both.

(6) The Patrol Commander may delay or terminate the ACWS at any time to ensure safety. Such action may be justified as a result of weather, traffic density, spectator operation or participant behavior.

Dated: May 2, 2012.

V.B. Gifford, Jr.,

Captain, U.S. Coast Guard, Captain of the Port Southeastern New England.

[FR Doc. 2012–11557 Filed 5–11–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0315]

RIN 1625–AA00

Safety Zone; Upper Mississippi River, Mile 183.0 to 183.5

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all waters of the Upper Mississippi River, from mile 183.0 to mile 183.5, in the vicinity of the Merchants Bridge and extending the entire width of the river. This safety zone is needed to protect repair workers and vessels transiting the area on the Upper Mississippi River to complete bridge repairs. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port Upper Mississippi River or a designated representative.

DATES: *Effective Date:* This rule is effective in the CFR from May 14, 2012 until 7 p.m. on December 31, 2012. This rule is effective with actual notice for purposes of enforcement beginning 7 a.m. on April 10, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2012–0315 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2012–0315 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are 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 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Chief Petty Officer Ryan Christensen, Sector Upper Mississippi River Waterways Management Department at telephone 314–269–2721, email