

**FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, filed a supplement to NADA 141-291 that provides for use of VETORYL (trilostane) Capsules in dogs for treatment of pituitary-dependent hyperadrenocorticism and for treatment of hyperadrenocorticism due to adrenocortical tumors. The supplement provides for the use of a 10-milligram capsule size. The supplemental NADA is approved as of June 5, 2009, and the regulations are amended in 21 CFR 520.2598 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

**§ 520.2598 [Amended]**

■ 2. In paragraph (a) of § 520.2598 remove "30 or 60 milligrams" and in its place add "10, 30, or 60 milligrams".

Dated: June 19, 2009.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. E9-15152 Filed 6-25-09; 8:45 am]

**BILLING CODE 4160-01-S**

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

[Docket No. USCG-2009-0405]

RIN 1625-AA00

**Safety Zone; Harborfest 2009, Parade of Sail, Elizabeth River, Norfolk, VA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a mobile safety zone on the Elizabeth River in the vicinity of Sewell's Point, Virginia, to Town Point Park, Norfolk, Virginia, in support of the Parade of Sail event taking place in conjunction with Harborfest 2009. This action is intended to restrict vessel traffic on the Elizabeth River to protect mariners from the hazards associated with marine parade events.

**DATES:** This rule is effective from 10 a.m. July 3, 2009 through 3 p.m. on July 5, 2009.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0405 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-2009-0405 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 following location: 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 temporary rule, call or e-mail LT Tiffany Duffy, Chief, Waterways Management Division, Coast Guard; telephone 757-668-5580, e-mail [Tiffany.A.Duffy@uscg.mil](mailto:Tiffany.A.Duffy@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**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters.

Additionally, this temporary safety zone will be enforced for approximately 4 hours on Friday, July 3, 2009 and for approximately 4 hours on Sunday, July 5, 2009 while the Parade of Sail arrives at and departs Town Point Park. This safety zone should have a minimal impact on vessel transits because mariners are not precluded from using any portion of the waterway except the safety zone area.

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** as any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters.

**Background and Purpose**

During the period of July 3 through July 5, 2009, the City of Norfolk and Norfolk Festevents Ltd. will sponsor Harborfest 2009, which includes the Parade of Sail event. This event will include a parade of more than twenty ships from around the world departing from Sewell's Point, Virginia enroute to Town Point Park, Norfolk, Virginia on July 3, 2009. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of spectators and transiting vessels. The Coast Guard anticipates numerous spectator craft for these scheduled events. Operators should expect significant vessel congestion along the parade route and viewing areas. The purpose of this regulation is to promote maritime safety and protect participants and the boating public in

the Port of Hampton Roads during the Parade of Sail event. For the safety concerns noted and to address the need for vessel control and vessel safety, all vessel traffic will be temporarily restricted in the vicinity of the parade route to provide for the safety of participants, spectators and transiting vessels.

#### Discussion of Rule

The Coast Guard is establishing a safety zone on specified waters of the Elizabeth River from Sewell's Point, Virginia to Town Point Park, Norfolk, Virginia. This safety zone will encompass all navigable waters within 300 yards ahead of, 100 yards abeam of, and all waters between participating vessels transiting from Sewell's Point enroute to Town Point Park, Norfolk, VA. This regulated area will be established in the interest of public safety during the Parade of Sail and will be enforced during the Parade of Sail on July 3, 2009, from approximately 11 a.m. until 3 p.m. and from approximately 11 a.m. until 3 p.m. on July 5, 2009 as the Parade of Sail departs Town Point Park, Norfolk, Virginia. Access to the safety zone will be restricted during the specified date and times. Except for participants and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

#### 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. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

#### 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 the specified portion of the Elizabeth River from 11 a.m. to 3 p.m. on July 3, 2009 and July 5, 2009.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be enforced for only about 4 hours on July 3 and July 5, 2009, and vessel traffic will be able to navigate safely around the zone. In addition, before the effective period begins, the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

#### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer 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–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,

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 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 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.ID, 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 which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves establishing a mobile safety zone around a parade of vessels and is expected to have no impact on the water. This zone is designed to protect mariners from the hazards associated with vessel parades. 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, and 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. 1226, 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 and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05-0405 to read as follows:

#### § 165.T05-0405 Safety Zone: Harborfest 2009, Parade of Sail, Elizabeth River, Norfolk, VA.

(a) *Regulated Area:* The following area is a safety zone: specified waters of the Elizabeth River 300 yards ahead of, 100 yards abeam of, and all waters between all vessels participating in the Parade of Sail, transiting from Sewell’s Point, Virginia enroute to Town Point Park, Norfolk, Virginia.

(b) *Definition:* For the purposes of this part, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulations:* (1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone number (757) 638-6641.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF-FM marine band radio channel 13 (165.65Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement Period:* This regulation will be in effect from 10 a.m. July 3, 2009 to 3 p.m. on July 5, 2009.

Dated: June 16, 2009.

**M.S. Ogle,**

*Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.*

[FR Doc. E9-15191 Filed 6-25-09; 8:45 am]

BILLING CODE 4910-15-P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R05-OAR-2007-1131; FRL-8921-5]

#### Approval and Promulgation of Air Quality Implementation Plans; Illinois; Oxides of Nitrogen Regulations, Phase II

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is approving a request submitted by the Illinois Environmental Protection Agency (Illinois EPA) on October 23, 2007, to revise the Illinois State Implementation Plan (SIP). The State has submitted revisions to 35 Illinois Administrative Code (Ill. Adm. Code) parts 211 and 217. The submitted revisions are final and adopted in the Ill. Adm. Code, and pertain to definitions and general provisions, and control of Nitrogen Oxides (NO<sub>x</sub>). The rules satisfy the requirements of EPA’s NO<sub>x</sub> SIP Call Phase II Rule (the Phase II Rule). We are approving these regulations based on Illinois’ demonstration that the State will meet the emissions targets set forth in the Phase II Rule through reductions from stationary internal combustion (IC) engines and turbines which are identified in the NO<sub>x</sub> plan submittal. Limiting NO<sub>x</sub> emissions from IC engines and turbines will enable the State to meet the 7,055 ton reduction requirement contained in the Phase II Rule, thereby improving air quality and protecting the health of Illinois citizens.

**DATES:** This direct final will be effective August 25, 2009, unless EPA receives adverse comments by July 27, 2009. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R05-OAR-2007-1131, by one of the following methods:

1. <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
2. *E-mail:* [mooney.john@epa.gov](mailto:mooney.john@epa.gov).
3. *Fax:* (312) 692-2551.