

summaries of safety and effectiveness data and information submitted to support approval of these applications 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), these approvals qualify for 3 years of marketing exclusivity beginning June 25, 2003.

The agency has determined under 21 CFR 25.33(c) 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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for "PR Pharmaceuticals, Inc." and in the table in paragraph (c)(2) by numerically adding an entry for "067210" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

*	*	*	*	*
(c)	*	*	*	*
(1)	*	*	*	*

Firm name and address			Drug labeler code	
*	*	*	*	*
PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524.			067210	
*	*	*	*	*
(2) * * *				
Drug labeler code		Firm name and address		
*	*	*	*	*
067210		PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524.		
*	*	*	*	*

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Section 522.841 is added to read as follows:

§ 522.841 Estradiol benzoate.

(a) *Specifications.* The product consists of a vial of estradiol benzoate microspheres and a vial of diluent.

(1) Each milliliter (mL) of constituted suspension contains 10 milligrams (mg) estradiol benzoate.

(2) Each mL of constituted suspension contains 20 mg estradiol benzoate.

(b) *Sponsor.* See No. 067210 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.240 of this chapter.

(d) *Conditions of use.* It is used by subcutaneous injection as follows:

(1) *Suckling beef calves*—(i) *Amount.* 10 mg; 1 mL of the product described in paragraph (a)(1) of this section.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers fed in confinement for slaughter*—(i) *Amount*—(A) 20 mg; 1 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(A) of this section.

(B) 10 mg; 0.5 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations.* For subcutaneous injection in the ear only. The use of 20 mg (1 mL) in steers does not provide additional rate of gain improvement over 10 mg (0.5 mL). Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Heifers fed in confinement for slaughter*—(i) *Amount.* One mL (20 mg) of product described in paragraph (a)(2) of this section.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: July 25, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09-03-258]

RIN 1625-AE11

Regulated Navigation Area; 2003 Gravity Games, Cleveland Harbor, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will establish a temporary Regulated Navigation Area (RNA) during the 2003 Gravity Games in the Port of Cleveland, Ohio. This regulation is necessary to manage vessel traffic in a portion of Cleveland Harbor. This regulation is intended to restrict vessel traffic from a portion of Lake Erie.

DATES: This rule is effective from 12 p.m. on Saturday, September 6, 2003 until 12 p.m. on Monday, September 15, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD09-03-258 and are available for inspection or copying at Coast Guard MSO Cleveland

between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Allen Turner, Chief, Port Operations Department, Coast Guard MSO Cleveland at (216) 937-0128.

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 under 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**. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments previously with regard to this event.

Background and Purpose

During the 2003 Gravity Games, the Wakeboard Competition will take place in Cleveland Harbor north of Voinovich Park. A regulated navigation area (RNA) will be established inside Cleveland's break wall to protect competitors and course obstacles (jumps, rails, etc.) from excessive speed and wakes, and to prevent interference with the competition.

Discussion of Rule

The RNA will be established from 12 p.m. on Saturday, September 6, 2003 until 12 p.m. on Monday, September 15, 2003. The RNA will encompass Cleveland Harbor, between Dock 28 of Cleveland Port Authority and the western edge of Burke Lake Front Airport, to include the Rock and Roll Museum Inner Harbor. No vessel shall exceed 5 mph nor produce a wake within the RNA. Any vessel within the RNA shall not pass within 50 feet of a moored obstacle. Any vessel within the RNA shall not enter the Rock and Roll Museum inner harbor. Any vessel within the RNA must adhere to the direction of the Patrol Commander or other official patrol craft. No vessel shall transit the RNA during the Wakeboard Competition without permission from the Patrol Commander.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 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 this rule 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 rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DHS is unnecessary.

This determination was based on the actual location of the RNA within the waterways, since vessels can transit north of the harbor break wall to reach the Main Entrance Channel or easternmost entrance channel. Vessels will also be allowed to transit through the RNA with permission from the Patrol Commander.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant 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 would affect the following entities, some of which might be small entities: The owners or operators of commercial vessels intending to transit a portion of the RNA.

This RNA would not have a significant economic impact on a substantial number of small entities for the following reasons: Vessel traffic can safely pass north of the break wall, outside the RNA, during the competitions. In cases where recreational boat traffic congestion is greater than expected and consequently obstructs shipping channels, commercial traffic may be allowed to pass through the RNA under Coast Guard escort with the permission of the Patrol Commander. Before the effective period, the Coast Guard will issue maritime advisories to users who might be impacted through notification in the **Federal Register**, the Ninth Coast Guard District Local Notice to Mariners, and through Marine Information Broadcasts. Additionally, the Coast Guard has not received any reports from small entities negatively affected during previous similar events.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this 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 want to assist small entities in understanding this rule so that they can better evaluate its effects and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Cleveland (see **ADDRESSES**).

Collection of Information

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

Federalism

We have analyzed this rule under Executive Order 13132 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 would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule would 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

The Coast Guard has 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 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

The Coast Guard has 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule under Commandant Instruction M16475.1C, which guides 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 categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded under Figure 2-1, paragraph 35(a) of the Instruction, from further environmental documentation. A written categorical exclusion determination is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, 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; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 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 temporary § 165.T09-258 to read as follows:

§ 165.T09-258 Regulated Navigation Area; 2003 Gravity Games, Cleveland, Ohio.

(a) *Regulated navigation area.* All waters of Cleveland Harbor, including the Inner Harbor, encompassed by a line starting at 41°30'49" N, 081°41'37" W (northwest corner of Burke Lakefront Airport); then northwest to 41°31'02" N, 081°41'49" W; then southwesterly following the break wall to 41°30'41" N, 081°42'26" W; then southeasterly to 41°30'27" N, 081°42'13" W (extending directly across the harbor from the northwestern corner of Dock 28 of the Cleveland Port Authority to the break wall); then following the contours of the waterfront back to the point of origin including all portions of the Rock and Roll Museum inner harbor. These coordinates are based upon North American Datum 1983 (NAD 83).

(b) *Effective period.* This section will be in effect from 12 p.m. EST on Saturday, September 6, 2003 through 12 p.m. EST on Monday, September 15, 2003.

(c) *Special regulations.* (1) Vessels within the regulated navigation area (RNA) shall not exceed 5 miles per hour or shall proceed at no-wake speed, whichever is slower; and maintain headway conditions permitting.

(2) Vessels within the RNA shall not pass within 50 feet of a moored obstacle.

(3) Vessels within the RNA shall not enter the Rock and Roll Museum inner harbor.

(4) Vessels within the RNA must adhere to the direction of the Patrol Commander or other official patrol craft.

(5) No vessel shall transit the RNA during the Wakeboard Competition without permission from the Patrol Commander.

(6) Permission to deviate from the above rules must be obtained from the Captain of the Port or the Patrol Commander via VHF/FM radio, Channel 6 or by telephone at (216) 937-0111.

Dated: August 8, 2003.

Ronald F. Silva,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 03-21086 Filed 8-18-03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 124-4079a; FRL-7545-4]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants, Commonwealth of Pennsylvania; Withdrawal of Direct Final Rule; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to our receipt of adverse written public comments, EPA is withdrawing the direct final rule to approve Pennsylvania's section 111(d) plan for the Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills. In the direct final rule published on June 24, 2003 (68 FR 37421), EPA stated that if we received adverse written public comment by July 24, 2003, the rule would be withdrawn and would not take effect. EPA subsequently received a letter of adverse comments. EPA will address the comments received in a subsequent final action based upon the proposed action also published on June 24, 2003 (68 FR 37449). EPA will not institute a second comment period on this action.

DATE: The Direct final rule is withdrawn as of August 19, 2003.

FOR FURTHER INFORMATION CONTACT:

James B. Topsale, via mail at: Air Quality Analysis Branch, Mail Code 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; or via telephone at: (215) 814-2190; or via e-mail at: topsale.jim@epa.gov.

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Sulfur acid plants, Waste treatment and disposal.