

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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#### 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