only the final rule. Submission of recommendations does not preclude the Secretary from deciding to provide additional opportunity for prior notice and comment in the **Federal Register**.

(5) The Regional Administrator may approve, disapprove, or partially approve the Council's recommendation. If the Regional Administrator does not approve the Council's specific recommendation, the Regional Administrator must notify the Council in writing of the reasons for the action prior to the first Council meeting following publication of such decision.

(b) *Possible framework adjustment measures.* Measures that may be changed or implemented through framework action, provided that any corresponding management adjustments can also be implemented through a framework adjustment, include:

(1) Skate permitting and reporting;

(2) Skate overfishing definitions and related targets and thresholds;

(3) Prohibitions on possession and/or landing of individual skate species;

(4) Skate possession;

(5) Skate closed areas (and consideration of exempted gears and fisheries);

(6) Seasonal skate fishery restrictions and specifications;

(7) Target TACs for individual skate species;

(8) Hard TACs/quotas for skates, including species-specific quotas, fishery quotas, and/or quotas for non-directed fisheries;

(9) Establishing a mechanism for TAC set-asides to mitigate , conduct scientific research, or for other reasons;

(10) Onboard observer requirements;

(11) Gear modifications, requirements, restrictions, and/or prohibitions;

(12) Minimum and/or maximum sizes for skates;

(13) Adjustments to exemption area requirements, area coordinates and/or management lines established by the FMP;

(14) Measures to address protected species issues, if necessary;

(15) Description and identification of EFH;

(16) Description and identification of habitat areas of particular concern;

(17) Measures to protect EFH;

(18) Adjustments and or/resetting of the ''baseline'' of management measures in other, described in § 648.320(c);

(19) OY and/or MSY specifications; and

(20) Any other measures contained in the FMP.

(c) Emergency action. Nothing in this section is meant to derogate from the authority of the Secretary to take emergency action under section 305(c) of the Magnuson-Stevens Act.

§ 648.322 Skate possession and landing restrictions.

(a) *Skate wing possession and landing limit.* A vessel or operator of a vessel that has been issued a valid Federal skate permit under this part, provided the vessel fishes under an Atlantic sea scallop, NE multispecies, or monkfish DAS as specified at §§ 648.53, 648.82, and 648.92, respectively, unless otherwise exempted under paragraph (b) of this section, may fish for, possess, and/or land up to the allowable daily and per trip limits specified as follows:

(1) Possess up to 20,000 lb (9,072 kg) of skate wings (45,400 lb (20,593 kg) whole weight) per trip of greater than 24 hours in duration; or

(2) Land up to 10,000 lb (4,536 kg) of skate wings (22,700 lb (10,296 kg) whole weight) per trip of 24 hours or less in duration.

(b) *Bait Letter of Authorization (LOA).* A skate vessel owner or operator under this part may request and receive from the Regional Administrator an exemption from the skate wing possession limit restrictions, provided that the following requirements and conditions are met:

(1) The vessel owner or operator obtains an LOA. LOAs are available upon request from the Regional Administrator.

(2) The vessel owner/operator possesses and/or lands only whole skates less than 23 inches (58.42 cm) total length.

(3) The vessel owner or operator fishes for, possesses, or lands skates only for use as bait.

(4) Vessels that fish for, possess, and/or land any combination of skate wings and whole skates less than 23 inches (58.42 cm) total length must comply with the possession limit restrictions under paragraph (a) of this section for all skates or skate parts on board.

(5) Any vessel owner/operator meets the requirements at § 648.13(h).

(6) The vessel owner or operator possesses and lands skates in compliance with this subpart for a minimum of 1 month.

(c) *Prohibitions on possession of skates.* All vessels fishing in the EEZ portion of the Skate Management Unit are subject to the following prohibitions:

(1) A vessel may not retain, possess, or land barndoor or thorny skates taken in or from the EEZ portion of the Skate Management Unit.(2) A vessel may not retain, possess, or land smooth skates taken in or from the GOM RMA described at § 648.80(a)(1)(i).

[FR Doc. 03–21205 Filed 8–18–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Injectable or Implantable Dosage Form New Animal Drugs; Estradiol Benzoate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two new animal drug applications (NADAs) filed by PR Pharmaceuticals, Inc. The NADAs provide for subcutaneous injection, in the ear only, of a suspension implant of estradiol benzoate microspheres for increased rate of weight gain in suckling beef calves, and for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.

DATES: This rule is effective August 19, 2003.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524, filed NADA 141–040 that provides for use of CELERIN (estradiol benzoate), microspheres for constitution into a suspension, by subcutaneous injection in the ear only for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter. PR Pharmaceuticals, Inc., also filed NADA 141–041 that provides for use of CELERIN C (estradiol benzoate), also microspheres for constitution, by subcutaneous injection in the ear only for increased rate of weight gain in suckling beef calves. The NADAs are approved as of June 25, 2003, and the regulations are amended in 21 CFR part 522 by adding new § 522.841 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In addition, PR Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii),

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.

[FR Doc. 03–21113 Filed 8–18–03; 8:45 am]

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