

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Parts 510 and 522

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Certifier *S. Reese*

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 [*insert date of publication in the Federal Register*].

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

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*NADA 141-040
141-041*

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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.

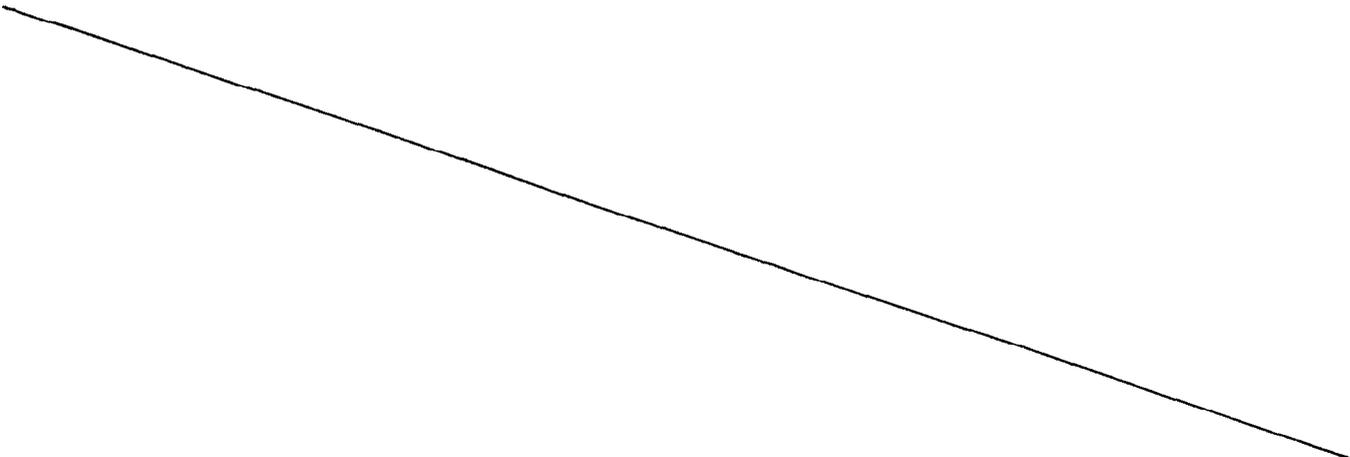
(B) For increased rate of weight gain.

(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: 7/25/07

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July 25, 2003.

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Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.
[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

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