

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DMB

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Center	JCE/LO

Implantation or Injectable 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 a supplemental new animal drug application (NADA) filed by PR Pharmaceuticals, Inc. The supplemental NADA provides 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. It also adds the indication for use for increased rate of weight gain in steers fed in confinement for slaughter, previously approved at a lower dose, to the higher approved dose level.

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: eric.dubbin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: PR Pharmaceuticals, Inc., 1716 Heath Pkwy., Fort Collins, CO 80524, filed a supplement to NADA 141-040 that provides for use of DURALEASE (estradiol benzoate) Microencapsulated Suspension Implant by subcutaneous injection in the ear for increased rate of weight gain in suckling beef calves. The supplemental NADA also adds the indication for use for

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increased rate of weight gain in steers fed in confinement for slaughter, previously approved at a lower dose, to the higher approved dose level. The supplemental NADA is approved as of January 19, 2006, and the regulations are amended in 21 CFR 522.841 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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(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 in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

- 2. In § 522.841, revise paragraph (d) to read as follows:

§ 522.841 Estradiol benzoate.

* * * * *

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

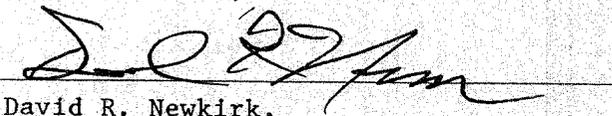
(1) *Amount and indications for use—(i) Suckling beef calves.* 10 mg (1 mL of product described in paragraph (a)(1) of this section or 0.5 mL of product described in paragraph (a)(2) of this section) for increased rate of weight gain.

(ii) *Cattle fed in confinement for slaughter.* 20 mg (1 mL of product described in paragraph (a)(2) of this section) for increased rate of weight gain and improved feed efficiency.

(2) *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: 2/8/06
February 8, 2006.



David R. Newkirk,
Acting Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

VERIFIED TO BE A TRUE
COPY OF THE ORIGINAL
COOLE

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