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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 529

Display Date 6/19/02
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Certifier G. Bentley

Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts

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 new animal drug application (NADA) filed by DEC International, Inc. The NADA provides for use of progesterone intravaginal inserts for manipulation of estrus in cattle.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Harlan J. Howard, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0231, e-mail: hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison WI 53708-8050, filed NADA 141-200 that provides for use of EAZI-BREED CIDR Progesterone Intravaginal Inserts for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers. The NADA is approved as of May 2, 2002, and the regulations in 21 CFR part 529 are amended by adding § 529.1940 to reflect the approval. The regulation in 21 CFR 522.690 is being amended to add a cross-reference for the concurrent use of dinoprost solution by intramuscular injection and is being revised to reflect a current format. The basis of approval is discussed in the freedom of information summary.

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NADA 141-200

NFR

In addition, DEC International, 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 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 Dockets Management Branch (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 (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning May 2, 2002.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

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 Parts 522 and 529

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 parts 510, 522, and 529 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 "DEC International, Inc." and in the table in paragraph (c)(2) by numerically adding an entry for "067080" 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
DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison, WI 53708-8050	067080

(2) * * *

Drug labeler code	Firm name and address
067080	DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison, WI 53708-8050

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 522.690 is revised to read as follows:

§ 522.690 Dinoprost solution.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

(b) *Sponsors.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle*—(i) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle*—(A) *Amount.* 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications.* For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle—(A) Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter may be used concurrently with progesterone intravaginal inserts as in § 529.1940 of this chapter.

(3) *Swine—(i) Amount.* 10 mg as a single intramuscular injection.

(ii) *Indications.* For parturition induction in swine when injected within 3 days of normal predicted farrowing.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 529 continues to read as follows:

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

6. Section 529.1940 is added to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains 1.38 grams of progesterone in molded silicone over a nylon spine.

(b) *Sponsor.* See No. 067080 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.540(a) of this chapter.

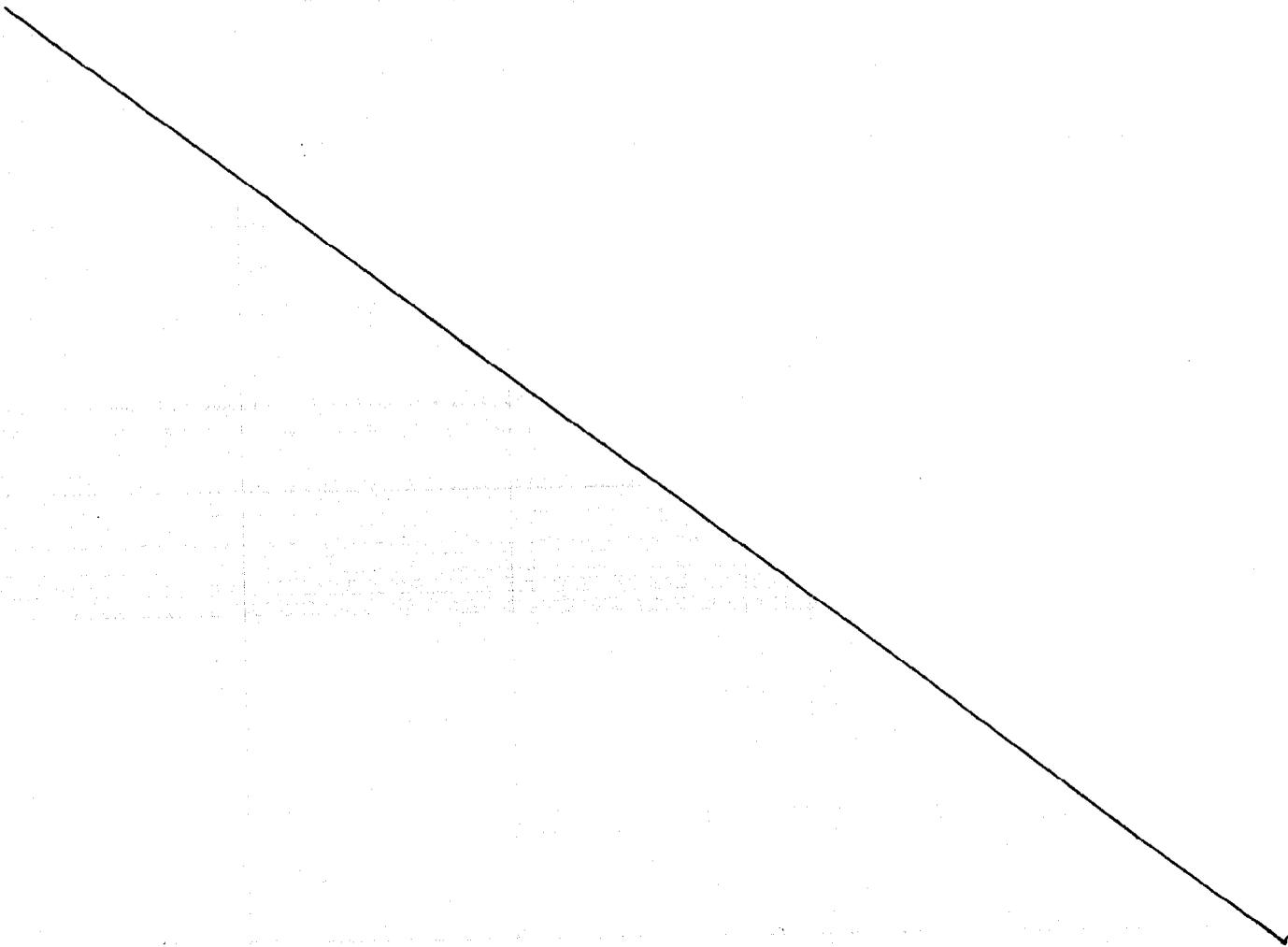
(d) *Special considerations.* (1) Wear latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed in accordance with applicable local, State, and Federal regulations.

(2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period. See § 522.690(c) of this chapter.

(e) *Conditions of use*—(1) *Amount*. Administer one intravaginal insert per animal for 7 days. Administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) 1 day prior to insert removal.

(2) *Indications for use*. For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.

(3) *Limitations*. Do not use in animals with abnormal, immature, or infected genital tracts; or in beef cows that are fewer than 20 days postpartum; or in beef or dairy heifers of insufficient size or age for breeding; or in lactating dairy cows. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be



disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter.

Dated: 6/6/02
June 6, 2002.

SF S
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Ch. Lowley