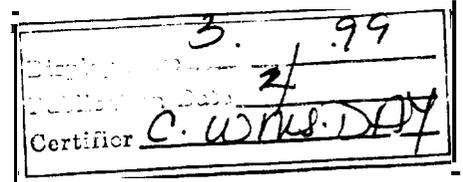


DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dinoprost Tromethamine Sterile Solution

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intramuscular use of dinoprost tromethamine sterile solution in cattle, swine, and mares.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-253 that provides for use of ProstaMate™ (dinoprost tromethamine injection) for intramuscular, veterinary prescription use for estrus synchronization, treatment of unobserved (silent) estrus and pyometra (chronic endometritis) in cattle; for abortion of feedlot and other nonlactating cattle; for parturition induction in swine; and for controlling the timing of estrus in estrous cycling mares and clinically anestrous mares that have a corpus luteum.

Approval of Phoenix's ANADA 200-253 for ProstaMate™ (dinoprost tromethamine injection) sterile solution is as a generic copy of Pharmacia & Upjohn's NADA 108-901 Lutalyse® (dinoprost

tromethamine) sterile solution. ANADA 200-253 is approved as of February 12, 1999, and the regulations are amended in 21 CFR 522.690(b) 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 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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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 redelegate to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

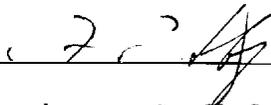
1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.690 [Amended]

2. Section 522.690 *Dinoprost tromethamine sterile solution* is amended in paragraph (b) by removing “No. 000009” and adding in its place “Nos. 000009 and 059130”.

Dated: 3/18/99
March 18, 1999



Stephen F. Sundlof
Director
Center for Veterinary
Medicine

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

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