DATES: This rule is effective July 26, 2000.

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

SUPPLEMENTARY INFORMATION: Abbott Laboratories, Chemical and Agricultural Products Division, 1401 Sheridan Rd., North Chicago, IL 60064–6316, filed ANADA 200–279 that provides for intramuscular use of Ketaflo™ (ketamine hydrochloride injection, USP) containing the equivalent of 100 milligrams of ketamine base per milliliter (mg/mL) of sterile solution. The product is for veterinary prescription use, in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation, and in nonhuman primates for restraint.

Approval of Abbott Laboratories' ANADA 200–279 for Ketaflo™ (ketamine hydrochloride injection, USP) is as a generic copy of Fort Dodge Laboratories' NADA 45–290 for Vetalar® (ketamine hydrochloride injection equivalent to 100 mg/mL ketamine). The ANADA is approved as of June 13, 2000, and the regulations are amended in 21 CFR 522.1222a(c) 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.

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.

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by adding the number ''000074,'' after the number ''000010,''.

Dated: July 17, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–18871 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Heska Corp. to Pharmacia & Upjohn Co.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525, has informed FDA that it has transferred to Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199 ownership of, and all rights and interests in NADA 141–082. Accordingly, the agency is amending the regulations in 21 CFR 522.778 to reflect the transfer of ownership.

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.

§ 522.778 [Amended]

2. Section 522.778 *Doxycycline hyclate* is amended in paragraph (b) by removing ''063604'' and adding in its place ''000009''.

Dated: July 18, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00–18825 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 supplemental new animal drug applications (NADA's) filed by Hoechst Roussel Vet. The supplemental NADA's provide for use of two additional trenbolone acetate and estradiol ear implants, one for heifers fed in confinement for slaughter for increased rate of weight gain, and the other for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, PO Box 4010, Clinton, NJ 08809–4010, filed supplemental NADA 140–897 that provides for Revalor®-IS ear implants containing 80 milligrams (mg) trenbolone acetate (TBA) and 16 mg estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Hoechst Roussel Vet also filed supplemental NADA 140–992 that provides for Revalor®-IH ear implants containing 80 mg TBA and 8 mg estradiol for heifers fed in confinement for slaughter for increased rate of weight gain.

The supplemental NADA's are approved as of June 19, 2000, and the regulations are amended in 21 CFR 522.2477 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

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 these applications 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning June 19, 2000, because the applications contain substantial evidence of the effectiveness of the drugs involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the applications and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the implants approved in these supplemental NADA's.

The agency has determined under 21 CFR 25.33(a)(2) 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. Section 522.2477 is amended by revising the first sentence in paragraph (b), by adding paragraph (d)(1)(i)(D), and by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii), (d)(2)(iii), and (d)(3) of this section. * * *

* * * * *

(d) * * *

(1) * * *

(i) * * *

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets), or 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(2) * * *

(i) *Amount.* (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B) of this section.

(B) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use.* (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

* * * * *

Dated: July 18, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00–18822 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

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 Elanco Animal Health. The supplemental NADA provides for use of monensin Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding for the prevention and control of coccidiosis, and increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). A technical correction is also being made.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735 that provides for use of RUMENSIN® 80 (80 grams per pound (g/lb) of monensin as monensin sodium) Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding to pasture cattle. The free-choice medicated mineral granules contain 1,620 g/ton monensin and are used for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). The supplemental NADA is approved as of July 7, 2000, and the regulations are amended in § 558.355(f)(3)(x) (21 CFR 558.355(f)(3)(x)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.355(d)(6) is revised to reflect current precautionary statements regarding the ingestion of monensin-containing formulations by unapproved species.