§ 500.49 [Removed]
4. Section 500.49 Chlorofluorocarbon propellant is removed.

PART 505—[REMOVED]
5. Part 505 is removed.

PART 507—[REMOVED]
6. Part 507 is removed.

PART 508—[REMOVED]
7. Part 508 is removed.

PART 510—NEW ANIMAL DRUGS
8. The authority citation for 21 CFR part 510 continues to read as follows:

§ 510.120 [Removed]
9. Section 510.120 Suspension of approval of new-drug applications for certain diethylstilbestrol and diethylstilbestrol-containing drugs is removed.

§ 510.200 [Removed]
10. Subpart C, consisting of § 510.200, is removed and reserved.

§ 510.310 [Removed]
11. Section 510.310 Records and reports for new animal drugs approved before June 20, 1963 is removed.

§ 510.413 [Removed]
12. Section 510.413 Chloroform used as an ingredient (active or inactive) in animal drug products is removed.

PART 570—FOOD ADDITIVES
13. The authority citation for 21 CFR part 570 continues to read as follows:

§ 570.22 [Removed]
14. Section 570.22 Safety factors to be considered is removed.
   Dated: July 3, 1996.
   William B. Schultz,
   Deputy Commissioner for Policy.
   [FR Doc. 96–18234 Filed 7–18–96; 8:45 am]
   BILLING CODE 4160–01–F

21 CFR Part 522
Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin Diacetate Tetrahydrate Injection

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 Intervet, Inc. The ANADA provides for intramuscular and intravenous use of a sterile injectable solution of gonadorelin diacetate tetrahydrate for treating ovarian cysts in female dairy cattle of breeding age.

EFFECTIVE DATE: July 19, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millisboro, DE 19966–0318, filed ANADA 200–134, which provides for intramuscular and intravenous use of Fertagyl® (gonadorelin diacetate tetrahydrate injection) for treatment of ovarian cysts in female dairy cattle of breeding age. Approval of ANADA 200–134 is as a generic copy of Rhone Merieux’s NADA 98–379 for Cystorelin® (gonadorelin diacetate tetrahydrate injection). The ANADA is approved as of June 17, 1996, and the regulations are amended by revising 21 CFR 522.1078(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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:

§ 522.1078 [Amended]
2. Section 522.1078 Gonadorelin diacetate tetrahydrate injection is amended in paragraph (b) by removing “No. 050604” and adding in its place “Nos. 050604 and 057926”.
   Dated: July 11, 1996.
   Stephen F. Sundlof,
   Director, Center for Veterinary Medicine.
   [FR Doc. 96–18350 Filed 7–18–96; 8:45 am]
   BILLING CODE 4160–01–F