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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510, 520, 522, and 558**

**New Animal Drugs; Change of Sponsor**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for six new animal drug applications (NADA's) from Roussel-UCLAF SA, Animal Health Division to Hoechst Roussel Vet.

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

**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:** Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France, has informed FDA that it has transferred ownership of, and all rights and interests in, the approved NADA's (130-951, 131-310, 138-612, 140-824, 140-897, and 140-992) to Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059.

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. Accordingly, the agency is amending the regulations in 21 CFR parts 510, 520, 522, and 558 to reflect the change of sponsor. The agency is also amending 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Roussel UCLAF SA because the firm no longer is the holder of any approved NADA's.

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## List of Subjects

### *21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

### *21 CFR Parts 520 and 522*

Animal drugs.

### *21 Part 558*

Animal Drugs, Animal Feeds.

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, 520, 522, and 558 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.

### **§ 510.600 [Amended]**

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Roussel-UCLAF SA” and in the table in paragraph (c)(2) by removing the entry for “012579”.

## **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

**§ 520.48 [Amended]**

4. Section 520.48 *Altrenogest solution* is amended in paragraph (b) by removing “012579” and adding in its place “012799”.

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 522.2476 [Amended]**

6. Section 522.2476 *Trenbolone acetate* is amended in paragraph (b) by removing “012579” and adding in its place “012799”.

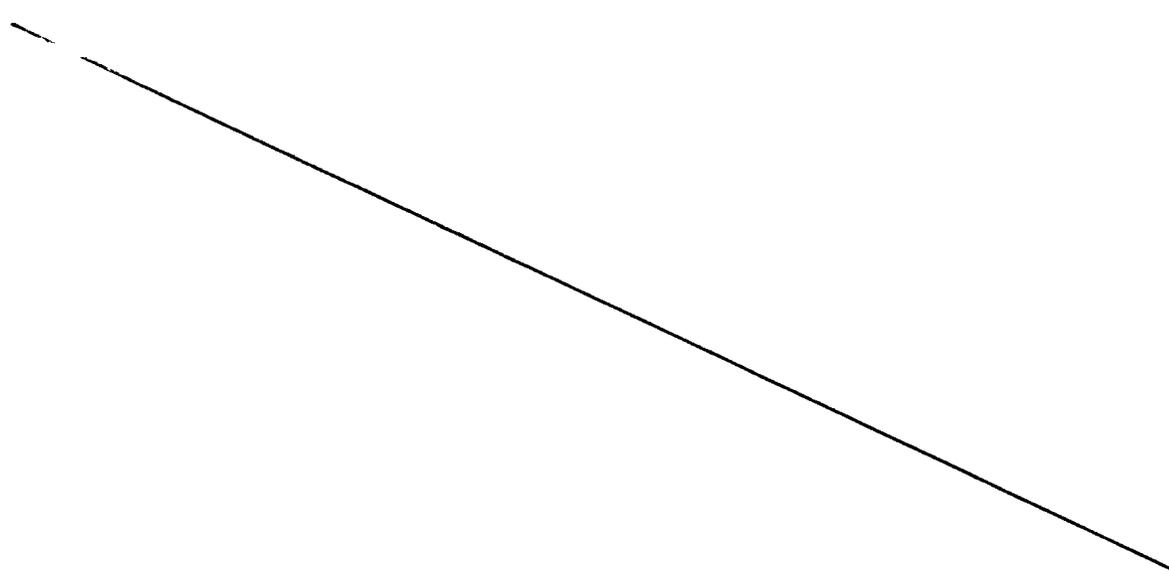
**§ 522.2477 [Amended]**

7. Section 522.2477 *Trenbolone acetate and estradiol* is amended in paragraph (a) by removing “012579” and adding in its place “012799”.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

8. The authority citation for 21 CFR part 558 continues to read as follows:

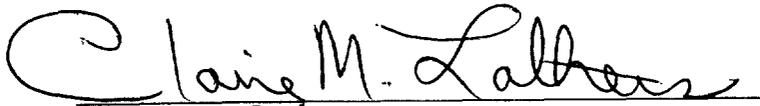
**Authority:** 21 U.S.C. 360b, 371.



§ 558.265 [Amended]

9. Section 558.265 *Halofuginone hydrobromide* is amended in paragraph (a) by removing “012579” and adding in its place “012799”.

Dated: 6/29/99  
June 29, 1999



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Center for Veterinary Medicine

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