

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 510, 520, and 524****Animal Drugs, Feeds, and Related Products; 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 the change of sponsor for two approved new animal drug applications (NADA's) from Mallinckrodt Veterinary Operations Inc., to Schering-Plough Animal Health Corp.

EFFECTIVE DATE: May 15, 1998.

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: Mallinckrodt Veterinary Operations, Inc., Mundelein, IL 60060, has informed FDA that it has transferred the ownership of and all rights and interests in the approved NADA's 102-020 (dichlorophene and toluene capsules) and 111-349 (selenium disulfide suspension) to Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083. The agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Mallinckrodt Veterinary Operations, Inc., because the firm no longer is the holder of any approved NADA's. The agency is also amending 21 CFR 520.580 and 524.2101 to reflect the change of sponsor.

List of Subjects*21 CFR Part 510*

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

21 CFR Parts 520 and 524

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, 520, and 524 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 "Mallinckrodt Veterinary Operations, Inc."; and in the table in paragraph (c)(2) by removing the entry for "015563".

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.

§ 520.580 [Amended]

4. Section 520.580 *Dichlorophene and toluene capsules* is amended in paragraph (b)(1) by removing "015563," and numerically adding "000061,".

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.2101 [Amended]

6. Section 524.2101 *Selenium disulfide suspension* is amended in paragraph (c) by removing "015563" and adding in its place "000061".

Dated: May 4, 1998.

Andrew J. Beaulieu,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol 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 a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for a revised warning against use of

florfenicol injectable solution in veal calves.

EFFECTIVE DATE: May 15, 1998.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ 07083-1982, is sponsor of NADA 141-063 Nuflor® Injectable Solution (300 milligrams florfenicol per milliliter) for veterinary prescription use for intramuscular treatment of cattle for bovine respiratory disease. Schering-Plough filed a supplemental NADA providing for a revised warning against use of the product in veal calves. The supplemental NADA is approved as of April 2, 1998, and the regulations are amended by revising 21 CFR 522.955(d)(1)(iii) 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, 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 25.33(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 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.

§ 522.955 [Amended]

2. Section 522.955 *Florfenicol solution* is amended in paragraph (d)(1)(iii) by removing the sentences