## 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.*

[FR Doc. 98–12960 Filed 5–14–98; 8:45 am]

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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

''Not for use in veal calves, calves under 1 month of age, or calves being fed an all milk diet. Use may cause violative tissue residues to remain beyond the withdrawal time.'' and adding in its place ''A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.''

Dated: May 4, 1998.

**Andrew J. Beaulieu,**

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

[FR Doc. 98–12961 Filed 5–14–98; 8:45 am]

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## PENSION BENEFIT GUARANTY CORPORATION

### 29 CFR Part 4044

### Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in June 1998.

**EFFECTIVE DATE:** June 1, 1998.

**FOR FURTHER INFORMATION CONTACT:** Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (For TTY/TDD users, call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

**SUPPLEMENTARY INFORMATION:** The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest assumptions. These interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest assumptions are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest assumptions for valuing benefits in plans with valuation dates during June 1998.

For annuity benefits, the interest assumptions will be 5.60 percent for the first 25 years following the valuation date and 5.25 percent thereafter. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These annuity and lump sum interest assumptions are unchanged from those in effect for May 1998.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during June 1998, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

**List of Subjects in 29 CFR Part 4044**

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

## PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

1. The authority citation for part 4044 continues to read as follows:

**Authority:** 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

2. In appendix B, a new entry is added to Table I, and Rate Set 56 is added to Table II, as set forth below. The introductory text of each table is republished for the convenience of the reader and remains unchanged.

**Appendix B to Part 4044—Interest Rates Used to Value Annuities and Lump Sums**

TABLE I.—ANNUITY VALUATIONS

[This table sets forth, for each indicated calendar month, the interest rates (denoted by $i_1$, $i_2$, * * * , and referred to generally as $i_t$) assumed to be in effect between specified anniversaries of a valuation date that occurs within that calendar month; those anniversaries are specified in the columns adjacent to the rates. The last listed rate is assumed to be in effect after the last listed anniversary date.]

| For valuation dates occurring in the month— | The values of $i_t$ are: | | | | | |
|---|---|---|---|---|---|---|
| | $i_t$ | for t = | $i_t$ | for t= | $i_t$ | for t = |
| * * * | * | | * | * | | * |
| June 1998 | .0560 | 1–25 | .0525 | >25 | N/A | N/A |