

as paragraphs (a), (c), and (d), respectively; by revising newly redesignated paragraph (a); by amending newly redesignated paragraph (d) by adding two new sentences after the fifth sentence; and by adding a new paragraph (b) to read as follows:

§ 520.2325a Sulfaquinoxaline drinking water.

(a) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors.

(1) No. 050749 for use of a 25-percent soluble powder and a 20-percent solution as provided for in paragraph (c) of this section.

(2) No. 060594 for use of 3.44- and 12.85-percent solutions as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(3) No. 017144 for use of a 34-percent solution as provided for in paragraphs (c)(1), (c)(2), (c)(3), (c)(4)(i), and (c)(4)(ii) of this section.

(b) *Related tolerances.* See § 556.685 of this chapter.

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(d) *Limitations.* * * * A withdrawal period has not been established for sulfaquinoxaline in preruminating calves. Do not use in calves to be processed for veal. * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.685 is added to subpart B read as follows:

§ 556.685 Sulfaquinoxaline.

A tolerance of 0.1 part per million is established for negligible residues of sulfaquinoxaline in the uncooked edible tissues of chickens, turkeys, calves, and cattle.

Dated: April 15, 1996.

Robert C. Livingston,
Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 96-11927 Filed 5-14-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 520 and 558

Animal Drugs, Feeds, and Related Products; 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 supplemental new animal drug applications (NADA's) filed by Elanco Animal Health, Division of Eli Lilly and Co., Moorman Manufacturing Co., and Farmland Industries, Inc. Elanco's supplemental NADA provides for use of monensin Type C medicated feeds fed to pasture cattle weighing less than 400 pounds (lb) for increased rate of weight gain. Moorman's and Farmland's supplemental NADA's provide for use of monensin blocks for pasture cattle weighing less than 400 lb for increased rate of weight gain.

EFFECTIVE DATE: May 15, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95-735, which provides for use of monensin Type A medicated articles to make monensin Type C medicated feeds containing 25 to 400 grams per ton monensin as monensin sodium to be fed at 50 to 200 milligrams per head per day to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) weighing less than 400 lb for increased rate of weight gain. Moorman Manufacturing Co., Quincy, IL 62301, filed supplemental NADA 115-581, and Farmland Industries, Inc., Kansas City, MO 64116, filed supplemental NADA 118-509, providing for free-choice feeding of monensin blocks, all to pasture cattle weighing less than 400 lb for increased rate of weight gain.

The supplemental NADA's provide for removal of the restriction concerning feeding of the products to animals weighing less than 400 lb body weight as currently approved. The supplemental NADA's are approved as of March 15, 1996, and the regulations are amended in 21 CFR 520.1448a(c) and 558.355(f)(3)(iii) and (f)(3)(v) to reflect the approvals. The basis for approval is discussed in the freedom of information summary for Elanco's supplemental NADA 95-735.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of Elanco Animal Health's supplemental NADA 95-735 qualifies for 3 years of marketing exclusivity beginning March 15, 1996, because the supplement contains reports of new clinical or field investigations (other than

bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to the new use of the product.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval of Moorman's supplemental NADA 115-581 and Farmland's supplemental NADA 118-509 do not qualify for marketing exclusivity because the supplements do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

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 basis of approval of Moorman's and Farmland's supplemental NADA's are by authorization to reference data and information in Elanco's supplemental NADA 95-735. Therefore, a freedom of information summary of the data and information required for approval of these NADA's is available under Elanco's supplemental NADA 95-735.

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

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

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

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1448a [Amended]

2. Section 520.1448a *Monensin blocks* is amended in paragraph (c)(4)(iii) by removing the phrase "weighing more than 400 pounds".

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

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

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

4. Section 558.355 *Monensin* is amended in paragraph (f)(3)(iii) (b) and (f)(3)(v) (b) by removing the phrase "weighing more than 400 pounds".

Dated: April 4, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 96-12156 Filed 5-14-96; 8:45 am]

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**PENSION BENEFIT GUARANTY
CORPORATION****29 CFR Parts 2619 and 2676****Valuation of Plan Benefits in Single-
Employer Plans; Valuation of Plan
Benefits and Plan Assets Following
Mass Withdrawal; Amendments
Adopting Additional PBGC Rates**

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Valuation of Plan Benefits in Single-Employer Plans and Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal. The former regulation contains the interest assumptions that the PBGC uses to value benefits under terminating single-employer plans. The latter regulation contains the interest assumptions for valuations of multiemployer plans that have undergone mass withdrawal. The amendments set out in this final rule adopt the interest assumptions applicable to single-employer plans with termination dates in June 1996, and to multiemployer plans with

valuation dates in June 1996. The effect of these amendments is to advise the public of the adoption of these assumptions.

EFFECTIVE DATE: June 1, 1996.

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 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: This rule adopts the June 1996 interest assumptions to be used under the Pension Benefit Guaranty Corporation's regulations on Valuation of Plan Benefits in Single-Employer Plans (29 CFR part 2619, the "single-employer regulation") and Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR part 2676, the "multiemployer regulation").

Part 2619 sets forth the methods for valuing plan benefits of terminating single-employer plans covered under title IV of the Employee Retirement Income Security Act of 1974, as amended. Under ERISA section 4041(c), all single-employer plans wishing to terminate in a distress termination must value guaranteed benefits and "benefit liabilities," *i.e.*, all benefits provided under the plan as of the plan termination date, using the formulas set forth in part 2619, subpart C. (Plans terminating in a standard termination may, for purposes of the Standard Termination Notice filed with PBGC, use these formulas to value benefit liabilities, although this is not required.) In addition, when the PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart C formulas to determine the amount of the plan's underfunding. Part 2676 prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219(c)(1)(D) and 4281(b) of ERISA.

Appendix B to part 2619 sets forth the interest rates and factors under the single-employer regulation. Appendix B to part 2676 sets forth the interest rates and factors under the multiemployer regulation. Because these rates and factors are intended to reflect current conditions in the financial and annuity markets, it is necessary to update the rates and factors periodically.

The PBGC issues two sets of interest rates and factors, one set to be used for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. The same assumptions apply to terminating single-employer plans and to

multiemployer plans that have undergone a mass withdrawal. This amendment adds to appendix B to parts 2619 and 2676 sets of interest rates and factors for valuing benefits in single-employer plans that have termination dates during June 1996 and multiemployer plans that have undergone mass withdrawal and have valuation dates during June 1996.

For annuity benefits, the interest rates will be 6.20% for the first 20 years following the valuation date and 4.75% thereafter. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 5.00% for the period during which benefits are in pay status, 4.25% during the seven-year period directly preceding the benefit's placement in pay status, and 4.0% during any other years preceding the benefit's placement in pay status. The above annuity interest assumptions represent an increase (from those in effect for May 1996) of .20 percent for the first 20 years following the valuation date and are otherwise unchanged. The lump sum interest assumptions are unchanged from those in effect for May 1996.

Generally, the interest rates and factors under these regulations are in effect for at least one month. However, the PBGC publishes its interest assumptions each month regardless of whether they represent a change from the previous month's assumptions. The assumptions normally will be published in the Federal Register by the 15th of the preceding month or as close to that date as circumstances permit.

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

Because of the need to provide immediate guidance for the valuation of benefits in single-employer plans whose termination dates fall during June 1996, and in multiemployer plans that have undergone mass withdrawal and have valuation dates during June 1996, the PBGC finds that good cause exists for making the rates and factors 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