

paragraphs (e)(1)(i) and (e)(1)(ii) in the "Sponsor" column by adding in numerical sequence "021641" to read as follows:

**§ 558.342 Melengestrol.**

\* \* \* \* \*

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 021641 for use of product described in paragraph (a)(2) of this section.

\* \* \* \* \*

Dated: December 29, 2004.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-761 Filed 1-13-05; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs For Use in Animal Feeds; Decoquinatate**

**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 two supplemental new animal drug applications (NADAs) filed by Alpharma Inc. The supplemental NADAs provide for the use of single-ingredient decoquinatate and

chlortetracycline Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at a broader range of concentrations.

**DATES:** This rule is effective January 14, 2005.

**FOR FURTHER INFORMATION CONTACT:**

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail:

*janis.messenheimer@fda.gov.*

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 141-147 for use of DECCOX (decoquinatate) and CHLORMAX (chlortetracycline) Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at the broader range of concentrations. Alpharma Inc. also filed a supplement to NADA 141-185 for use of DECCOX and AUREOMYCIN (chlortetracycline) Type A medicated articles for the same revised conditions of use. The supplemental applications are approved as of December 16, 2004, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

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.

**List of Subjects in 21 CFR 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 part 558 is amended as follows:

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

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

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

■ 2. Section 558.195 is amended by redesignating paragraphs (e)(2)(ii), (e)(2)(iii), and (e)(2)(iv) as paragraphs (e)(2)(vi), (e)(2)(iv), and (e)(2)(iii) respectively; and by adding new paragraphs (e)(2)(ii) and (e)(2)(vii) to read as follows:

**§ 558.195 Decoquinatate.**

\* \* \* \* \*

(e) \* \* \*

\* \* \* \* \*

(2) *Cattle.*

| Decoquinatate in grams/ton | Combination in grams/ton        | Indications for use  | Limitations   | Sponsor |
|----------------------------|---------------------------------|--|---|---------|
| *                          | *                               | *  | *   | *       |
| (ii) 12.9 to 90.8          | Chlortetracycline 500 to 4,000. | Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. | Feed Type C feed to provide 22.7 mg decoquinatate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinatate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141-147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141-185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter. | 046573  |

| Decoquinatate in grams/ton | Combination in grams/ton           | Indications for use  | Limitations   | Sponsor |
|----------------------------|------------------------------------|--|---|---------|
| *                          | *                                  | *  | *   | *       |
| (vii) 90.9 to 535.7        | Chlortetracycline 4,000 to 20,000. | Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> ; and for treatment of bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. | Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg decoquinatate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinatate per 100 lb body weight per day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141-147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141-185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter. | 046573  |

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Dated: January 7, 2005.

**Steven D. Vaughn,**

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

[FR Doc. 05-789 Filed 1-13-05; 8:45 am]

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**PENSION BENEFIT GUARANTY CORPORATION**

**29 CFR Parts 4022 and 4044**

**Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits**

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in February 2005. Interest assumptions are also published on the PBGC's Web site <http://www.pbgc.gov>.

**EFFECTIVE DATE:** February 1, 2005.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion, Acting Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, (202) 326-4024.

(TTY/TDD users may 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 regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

Accordingly, this amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during February 2005, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during February 2005, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined

using the PBGC's historical methodology for valuation dates during February 2005.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 4.00 percent for the first 20 years following the valuation date and 4.75 percent thereafter. These interest assumptions represent a decrease (from those in effect for January 2005) of 0.10 percent for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.00 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 interest assumptions are unchanged from those in effect for January 2005.

For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

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 and payment of benefits in plans with valuation dates during February 2005, the PBGC finds that good cause exists