

Sickness Insurance" and adding in its place "Director of Programs".

(e) Paragraph (c) is removed.

8. Section 375.8 is revised to read as follows:

#### **§ 375.8 Regulations for employers.**

(a) In a national emergency, as described in § 375.2, employers shall continue to follow, to the greatest extent possible, the requirements pertaining to employers in subchapters A, B, and C of this chapter.

(b) Where a national emergency, as described in § 375.2, prevents an employer from following any requirement imposed by paragraph (a) of this section, the employer shall comply with such requirement as soon as possible after the cessation of the national emergency.

(c) In a national emergency, as defined in § 375.2, all communications by employers shall be directed as set forth in § 375.4.

Dated: November 18, 1999.

By Authority of the Board.

**Beatrice Ezerski,**

*Secretary to the Board.*

[FR Doc. 99-30792 Filed 11-24-99; 8:45 am]

BILLING CODE 7905-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 520**

#### **Oral Dosage Form New Animal Drugs; Lincomycin Soluble Powder**

**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 an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and for broiler chickens for the control of necrotic enteritis.

**EFFECTIVE DATE:** November 26, 1999.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed ANADA 200-

233 that provides for use of Linco Soluble (lincomycin hydrochloride soluble powder) to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and for broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

The ANADA is approved as a generic copy of Pharmacia & Upjohn's NADA 111-636 Lincomix® Soluble Powder. ANADA 200-233 is approved as of September 22, 1999, and 21 CFR 520.1263c(b) is amended 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, 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 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.

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 520**

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 520 is 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:** 21 U.S.C. 360b.

#### **§ 520.1263c [Amended]**

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by adding at the end the sentence "Approval for use of 40-gram packet to No. 046573 in § 510.600(c) of this chapter".

Dated: November 10, 1999.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 99-30701 Filed 11-24-99; 8:45 am]

BILLING CODE 4160-01-F

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 520**

#### **Oral Dosage Form New Animal Drugs; Sulfamethazine Tablets**

**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 new animal drug application (NADA) filed by Lloyd, Inc. The NADA provides for oral use of sulfamethazine tablets for beef cattle and nonlactating dairy cattle to treat diseases caused by sulfamethazine sensitive organisms.

**EFFECTIVE DATE:** November 26, 1999.

**FOR FURTHER INFORMATION CONTACT:** Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

**SUPPLEMENTARY INFORMATION:** Lloyd, Inc., P.O. Box 86, 604 West Thomas Ave., Shenandoah, IA 51601, filed NADA 140-908 that provides for oral use of Veta-Meth (sulfamethazine) tablets for beef cattle and nonlactating dairy cattle to treat diseases caused by sulfamethazine sensitive organisms such as bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*F. necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis*, *E. zurnii*).

The NADA is approved as of September 16, 1999, and the regulations are amended in § 520.2260a(a)(1) (21 CFR 520.2260a(a)(1)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulation currently contains a paragraph reflecting that approval of NADA's were based on National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation

evaluations of the products and FDA's conclusions based on those evaluations. Enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988 has superseded the approval of NADA's based on NAS/NRC evaluations. At this time, the NAS/NRC status paragraph is removed.

Also, the heading of § 520.2260a is revised to include tablets in addition to oblets and boluses.

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, 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 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.

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 congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

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 520 is 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:** 21 U.S.C. 360b.

2. Section 520.2260a is amended by revising the section heading and paragraph (a)(1), and by removing paragraph (a)(4) to read as follows:

#### § 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690 in § 510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.

\* \* \* \* \*

Dated: November 10, 1999.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 99-30703 Filed 11-24-99; 8:45 am]

**BILLING CODE 4160-01-F**

#### PENSION BENEFIT GUARANTY CORPORATION

#### 29 CFR Part 4007

**RIN 1212-AA82**

#### Payment of Premiums

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** The PBGC is amending its regulation on Payment of Premiums to encourage self-correction of premium underpayments. The amendments make it easier to qualify for "safe-harbor" relief from late payment penalty charges and codify the PBGC's current premium penalty policy (under which the penalty charge is lowered from 5% per month to 1% per month if a premium payor corrects an underpayment before PBGC notification).

**DATES:** *Effective Date:* December 27, 1999.

*Applicability Dates:* The amendment to the safe-harbor rules will apply to PBGC initial determinations and final decisions on requests for reconsideration ("PBGC determinations") with respect to premiums for 1999 and later plan years, and to PBGC determinations issued on or after December 27, 1999 with respect to premiums for plan years beginning before 1999. The amendment to the late payment penalty rate will apply to PBGC determinations issued on or after December 27, 1999 with respect to premiums for 1996 and later plan years.

#### FOR FURTHER INFORMATION CONTACT:

Harold J. Ashner, Assistant General Counsel, or Catherine B. Klion, Attorney, Office of the General Counsel, PBGC, 1200 K Street, NW., Washington, DC 20005-4026; 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:** On April 27, 1999 (at 64 FR 22589), the PBGC published a proposed rule to amend its regulation on Payment of Premiums (29 CFR part 4007). The proposed amendments would make it easier to qualify for "safe-harbor" relief from late payment penalty charges and would codify the PBGC's current premium penalty policy (under which the penalty charge is lowered from 5% per month

to 1% per month if a premium payor corrects an underpayment before PBGC notification).

The PBGC received two comments on the proposed rule. Both commenters praised the PBGC's efforts to expand safe-harbor relief but suggested that the amendment to the safe-harbor rules, which in the proposed rule would have applied with respect to premiums for 1999 and later plan years, should apply with respect to premiums for prior plan years as well. In response to the comments, the PBGC will provide the expanded safe-harbor relief to all PBGC determinations issued on or after December 27, 1999 with respect to premiums for plan years beginning before 1999, as well as to all PBGC determinations with respect to premiums for 1999 and later plan years. Applying the expanded safe-harbor relief with respect to premiums for prior plan years will further encourage self-correction of premium underpayments. In all other respects, the PBGC is issuing the final regulation without change from the proposed regulation.

#### Amendment to Safe-Harbor Rules

The proposed rule expanded the PBGC's safe-harbor rules under the current regulation to encourage self-correction in three situations. As explained in detail in the preamble to the proposed rule, a plan's premium due dates depend upon whether the plan is "small" or "large." The determination of whether a plan is "small" or "large" is based on the actual number of participants for whom premiums were payable for the prior year (not necessarily the number of participants reported on the PBGC Form 1 for the prior year).

The premium filing due date for small plans (those with fewer than 500 participants for the prior year) for both the flat-rate premium (for single-employer and multiemployer plans) and the variable-rate premium (for single-employer plans) is the fifteenth day of the tenth full calendar month in the premium payment year. For calendar year plans, this date is October 15 of the premium payment year. (For convenience, the discussion in this preamble assumes that all plans are calendar year plans.)

For large single-employer and multiemployer plans (those with 500 or more participants for the prior year), the due date for the flat-rate premium is the last day of the second full calendar month in the premium payment year (February 28 of the premium payment year). If the number of participants for whom premiums are payable for the premium payment year is not known by