

El Paso, TX, El Paso Intl, RNAV (GPS) RWY 26L, Orig  
 El Paso, TX, El Paso Intl, RNAV (GPS) RWY 26R, Orig  
 El Paso, TX, El Paso Intl, GPS RWY 26L, Orig, CANCELLED  
 Houston, TX, West Houston, RNAV (GPS) Y RWY 33, Orig  
 Temple, TX, Draughton-Miller Central Texas Regional, LOC/DME BC RWY 33, Amdt 3A, CANCELLED  
 Wichita Falls, TX, Sheppard AFB/ Wichita Falls Muni, NDB RWY 33L, Amdt 11  
 Wichita Falls, TX, Sheppard AFB/ Wichita Falls Muni, VOR-D, Amdt 14  
 Wichita Falls, TX, Sheppard AFB/ Wichita Falls Muni, RNAV (GPS) RWY 15R, Orig  
 Wichita Falls, TX, Sheppard AFB/ Wichita Falls Muni, RNAV (GPS) RWY 33L, Orig  
 Evanston, WY, Evanston-Uinta County Burns Field, VOR/DME RWY 23, Amdt 2B  
 Evanston, WY, Evanston-Uinta County Burns Field, RNAV (GPS) RWY 5, Orig  
 Evanston, WY, Evanston-Uinta County Burns Field, RNAV (GPS) RWY 23, Orig  
 The FAA published the following procedure in Docket No. 30339; Amdt. No. 3031 to Part 97 of the Federal Aviation Regulations (Vol. 67, FR No. 225, Page 70155; dated Thursday, November 21, 2002) under section 97.29 effective November 28, 2002 which is hereby amended to be effective December 26, 2002:  
 Sacramento, CA, Sacramento Mather, ILS RWY 22L, Amdt 3

[FR Doc. 02-30441 Filed 12-2-02; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 520

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations for preslaughter withdrawal time for lincomycin soluble powder products used to make medicated drinking water for swine to correct inadvertent editorial errors. This

action is being taken to ensure accuracy and clarity in the agency's regulations.

**DATES:** This rule is effective December 3, 2002.

#### FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: ghaibel@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** FDA has found that § 520.1263c (21 CFR 520.1263c) does not reflect the approved preslaughter withdrawal time for three lincomycin soluble powder products used to make medicated drinking water for swine. The 6-day withdrawal time was inadvertently removed for a generic product approved under ANADA 200-189 at the time it was being removed for the pioneer product approved under NADA 111-636 (64 FR 13341, March 18, 1999). The conditions of use for two other products approved February 4, 1999, under ANADA 200-241 (64 FR 13508, March 19, 1999) and September 22, 1999, under ANADA 200-233 (64 FR 66382, November 26, 1999) were subsequently codified without a withdrawal period. At this time, the regulations are being amended in § 520.1263c to correct these errors.

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 (d)(1)(iii) by adding at the end the sentence "For Nos. 046573 and 051259: Do not slaughter swine for 6 days following last treatment."

Dated: November 8, 2002.

**Steven D. Vaughn,**

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

[FR Doc. 02-30639 Filed 12-2-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Ivermectin Paste

**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 Virbac AH, Inc. The ANADA provides for oral use of ivermectin paste in horses for treatment and control of various internal parasites or parasitic conditions.

**DATES:** This rule is effective December 3, 2002.

#### FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed ANADA 200-320 for EQUELL (ivermectin) Paste. The application provides for oral use of 1.87 percent ivermectin paste in horses for the treatment and control of various species of internal parasites or parasitic conditions. Virbac's EQUELL Paste is approved as a generic copy of Merial Limited's EQUALEN Paste, approved under NADA 134-314. ANADA 200-320 is approved as of August 9, 2002, and 21 CFR 520.1192 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 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.

#### § 520.1192 [Amended]

2. Section 520.1192 *Ivermectin paste* is amended in paragraph (b)(2) by removing "No." and by adding in its place "Nos. 051311 and".

Dated: November 18, 2002.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 02–30640 Filed 12–2–02; 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; Ractopamine and Tylosin

**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 Elanco Animal Health. The supplemental NADA provides for use of ractopamine and tylosin single-ingredient Type A medicated articles to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, increased carcass leanness; and for the prevention of swine dysentery in finishing swine.

**DATES:** This rule is effective December 3, 2002.

#### FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600, e-mail: candres@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–172 that provides for use of PAYLEAN (9 or 45 grams per pound (g/lb) ractopamine hydrochloride) and TYLAN (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for the prevention of swine dysentery in finishing swine. The supplemental NADA is approved as of June 19, 2002, and the regulations are amended in § 558.500 (21 CFR 558.500) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.500 is being revised to reflect a current format. The entire text of this section is being provided for the convenience of the reader.

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)(2) 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 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 558.500 is revised to read as follows:

#### § 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.*

(1) Labeling of Type B and Type C swine feeds shall bear the following:

(i) "Caution: Pigs fed PAYLEAN are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of PAYLEAN."

(ii) "Not for use in breeding swine."

(2) Tylosin in combinations as tylosin phosphate.

(e) *Conditions of use.* (1) Swine—

| Ractopamine in grams/ton | Combination in grams/ton | Indications for use   | Limitations                       | Sponsor |
|--------------------------|--------------------------|---|-----------------------------------|---------|
| (i) 4.5                  |                          | For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight. | Feed continuously as sole ration. | 000986  |