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.

■ 2. Sections 522.1660 and 522.1660a are redesignated as §§ 522.1660a and 522.1660b, respectively, and new § 522.1660 is added to read as follows:

§ 522.1660 Oxytetracycline injectable solutions.

■ 3. Newly redesignated § 522.1660a is amended by revising paragraphs (b) and (c), by redesignating paragraph (d) as paragraph (e), by revising newly redesignated paragraph (e), and by adding new paragraph (d) to read as follows:

§ 522.1660a Oxytetracycline injection, 200 milligrams/milliliter.

(a) * * *

(b) *Sponsors.* See Nos. 000010, 000069, 011722, 053389, 055529, 057561, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(e) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including prerumenative (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis*.

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*.

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

■ 4. Newly redesignated § 522.1660b is amended in paragraph (e)(1)(ii) by removing ''milliliter'' and by adding in its place ''mL'', by removing paragraph (e)(2)(ii), by redesignating paragraph (e)(2)(iii) as new paragraph (e)(2)(ii) and removing ''milliliter'' and by adding in its place ''mL'', and by revising paragraph (e)(2)(i) to read as follows:

§ 522.1660b Oxytetracycline injection, 300 milligrams/milliliter.

* * * * *

(e) * * *

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

* * * * *

Dated: May 20, 2004.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–12839 Filed 6–7–04; 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; Tiamulin and Chlortetracycline

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 Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing tiamulin hydrogen fumarate and chlortetracycline hydrochloride to make two-way combination drug Type B and Type C medicated feeds for swine.

DATES: This rule is effective June 8, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200–356 for use of PENNCHLOR (chlortetracycline hydrochloride) and DENAGARD (tiamulin hydrogen fumarate) Type A medicated articles to make two-way

combination drug Type B and Type C medicated feeds for swine. Pennfield Oil Co.'s ANADA 200–356 is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 141–011. The ANADA is approved as of April 6, 2004, and the regulations are amended in 21 CFR 558.600 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 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 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)(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.

§ 558.600 [Amended]

■ 2. Section 558.600 is amended in the table in paragraph (e)(1)(iii) in the ''Sponsor'' column by numerically adding ''053389''.

Dated: May 18, 2004.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–12838 Filed 6–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

Mechanical Power—Transmission Apparatus; Mechanical Power Presses; Telecommunications; Hydrogen

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule; technical amendments.

SUMMARY: This final rule corrects errors in four OSHA standards. The first correction deletes two references to a nonexisting table in the Mechanical Power-Transmission Apparatus Standard. The second is a correction of typographical errors in the Mechanical Power Presses Standard. The third correction is to a cross-reference in the Telecommunications Standard. The fourth correction is to a reference to a table contained in the Hazardous Materials Standard for Hydrogen.

DATES: This final rule becomes effective on June 8, 2004.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact George Shaw, Acting Director, Office of Communications, Room N3637, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999 or fax: (202) 693–1635. For technical information, contact Kenneth Stevanus, Office of Engineering Safety, Room N3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2260.

SUPPLEMENTARY INFORMATION:

I. Mechanical Power-Transmission Apparatus

OSHA standards 29 CFR 1910.219 and 29 CFR 1926.307 contain requirements for the construction of guards for all types of mechanical power-transmission apparatus. On November 24, 1978, OSHA revoked certain safety and health standards, including Tables O–12 and O–13 in 29 CFR 1910.219 (43 FR 49726, 49741). These tables contained specifications for materials used in guarding mechanical power-transmission apparatus. They were revoked because they were considered overly detailed and too restrictive of the kinds of materials used for guards (43 FR 49740). Further, all references to these two tables were also to be removed. However, OSHA neglected to remove two references to Table O–12.

The first reference to Table O–12 that still appears is found in paragraph (e)(1)(i) of 29 CFR 1910.219 and paragraph (e)(1)(i) of 29 CFR 1926.307, both of which read as follows:

> Where both runs of horizontal belts are seven (7) feet or less from the floor level, the guard shall extend to at least fifteen (15) inches above the belt or to a standard height (see Table O–12), except that where both runs of a horizontal belt are 42 inches or less from the floor, the belt shall be fully enclosed in accordance with paragraphs (m) and (o) of this section. [Emphasis added.]

The second reference to Table O–12 is found in paragraph (o)(5)(ii) of 29 CFR 1910.219 and paragraph (o)(5)(ii) of 29 CFR 1926.307, both of which read as follows:

> Posts shall be not more than eight (8) feet apart; they are to be permanent and substantial, smooth, and free from protruding nails, bolts, and splinters. If made of pipe, the post shall be one and one-fourth (1¼) inches inside diameter, or larger. If made of metal shapes or bars, their section shall be equal in strength to that of one and one-half (1½) by one and one-half (1½) by three-sixteenths (3⁄16) inch angle iron. If made of wood, the posts shall be two by four (2 × 4) inches or larger. The upper rail shall be two by four (2 × 4) inches, or two one by four (1 × 4) strips, one at the top and one at the side of posts. The midrail may be one by four (1 × 4) inches or more. Where panels are fitted with expanded metal or wire mesh as noted in Table O–12, the middle rails may be omitted. Where guard is exposed to contact with moving equipment, additional strength may be necessary. [Emphasis added.]

OSHA is removing the text referring to Table O–12 from all four of these paragraphs.

II. Mechanical Power Presses

On December 3, 1974, OSHA published in the **Federal Register** (39 FR 41841) a final rule on Mechanical Power Presses based on a petition to revoke 29 CFR 1910.217(d)(1) and (d)(2). As part of the final rule, a new paragraph (c)(5) was added, reading, in part, as follows:

> Where the operator feeds or removes parts by placing one or both hands in the point of operation, and a two hand control, presence sensing device of Type B gate or movable barrier (on a part revolution clutch) is used for safeguarding:

The paragraph as printed contains typographical errors that change the meaning of the paragraph and imply that a Type-B gate is a presence-sensing device. This is not the case. A Type-B gate is considered a safety device when used with a failsafe control system and a brake monitor.