**Effective Date**

(h) This amendment becomes effective on July 13, 2004.

Issued in Renton, Washington, on May 26, 2004.

**Kevin M. Mullin,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04–12571 Filed 6–7–04; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510 and 520

### New Animal Drugs; Change of Sponsor

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADAs) from Zema Corp. to Virbac AH, Inc.

**DATES:** This rule is effective June 8, 2004.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

**SUPPLEMENTARY INFORMATION:** Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

| Application No. | 21 CFR Section | Trade Name |
|---|---|---|
| NADA 102–942 | 520.580 | PULVEX Multi-purpose Worm Caps |
| NADA 091–260 | 520.1804 | PULVEX Worm Caps |

Accordingly, the agency is amending the regulations in 21 CFR 520.580 and 520.1804 to reflect the transfer of ownership.

Following these changes of sponsorship, Zema Corp. is no longer the sponsor of an approved application. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to remove the entries for Zema Corp.

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 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*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 parts 510 and 520 are amended as follows:

## PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.600 [Amended]**

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Zema Corp.'' and in the table in paragraph (c)(2) by removing the entry for ''050906''.

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

**§ 520.580 [Amended]**

■ 4. Section 520.580 is amended in paragraph (b)(1) by removing ''050906'' and by adding in its place ''051311''.

**§ 520.1804 [Amended]**

■ 5. Section 520.1804 is amended in paragraph (b) by removing ''050906'' and by adding in its place ''051311''.

Dated: May 19, 2004.

**Steven D. Vaughn,**

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

[FR Doc. 04–12840 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 522

### Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations for oxytetracycline injectable solutions. The regulations for oxytetracycline injectable solutions are also being revised to conform to a current format. These changes are being made to improve the organization and readability of the regulations.

**DATES:** This rule is effective June 8, 2004.

**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: *george.haibel@fda.gov*.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 19, 2003 (68 FR 54804), § 522.1660a (21 CFR 522.1660a) was added to reflect the approval of a 300-milligram (mg)/milliliter (mL) oxytetracycline injectable solution under NADA 141–143. At this time, we are redesignating and amending §§ 522.1660 (21 CFR 522.1660) and 522.1660a as §§ 522.1660a and 522.1660b, respectively. These sections are also being revised to conform to a current format. These changes are being made to improve the organization and readability of the regulations.

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 522**

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 522 is amended as follows:

## 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