

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

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 Pfizer, Inc. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle and in swine, by injection, for the management of respiratory disease. FDA is also amending the regulations to add the acceptable daily intake for total residues of tulathromycin and tolerances for residues of tulathromycin in edible tissues of cattle and swine.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141-244 for DRAXXIN (tulathromycin) Injectable Solution. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle, by subcutaneous injection, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD

associated with *M. haemolytica*, *P. multocida*, and *H. somni*; and in swine, by intramuscular injection, for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*. The application is approved as of May 24, 2005, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.2630 and in part 556 (21 CFR part 556) by adding § 556.745 to reflect the approval. The basis of approval is discussed in the freedom of information (FOI) summary.

In accordance with the FOI 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 24, 2005.

The agency has determined under 21 CFR 25.33(d)(5) 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 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 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 522 and 556 are 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. Section 522.2630 is added to read as follows:

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) *Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease

in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*.

(iii) *Limitations*. Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobaccillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, and *H. parasuis*.

(iii) *Limitations*. Swine intended for human consumption must not be slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.745 is added to read as follows:

§ 556.745 Tulathromycin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of tulathromycin is 15 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for CP-60,300 (the marker residue) is 5.5 parts per million (ppm).

(ii) [Reserved]

(2) *Swine*—(i) *Kidney (the target tissue)*. The tolerance for CP-60,300 (the marker residue) is 15 ppm.

(ii) [Reserved]

(c) *Related conditions of use*. See § 522.2630 of this chapter.

Dated: June 20, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S