

§ 404.1560(c)(1)). We also consider the opinion given by one or more medical or psychological consultants designated by the Commissioner. (See § 404.1616.)

(d) *Who is a designated medical or psychological consultant?* A medical or psychological consultant designated by the Commissioner includes any medical or psychological consultant employed or engaged to make medical judgments by the Social Security Administration, the Railroad Retirement Board, or a State agency authorized to make disability determinations, and includes a medical or psychological expert (as defined in § 405.5 of this chapter) in claims adjudicated under the procedures in part 405 of this chapter. A medical consultant must be an acceptable medical source identified in § 404.1513(a)(1) or (a)(3) through (a)(5). A psychological consultant used in cases where there is evidence of a mental impairment must be a qualified psychologist. (See § 404.1616 for limitations on what medical consultants who are not physicians can evaluate and the qualifications we consider necessary for a psychologist to be a consultant.)

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**Gregory Zwitich,**

*Social Security Regulations Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### 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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for the addition of a pathogen to the indication for use of tulathromycin in cattle, by injection, for the treatment of respiratory disease.

**DATES:** This rule is effective September 29, 2006.

**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.hhs.gov](mailto:joan.gotthardt@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-244 for DRAXXIN (tulathromycin) Injectable Solution. The supplemental NADA provides for the addition of a pathogen, *Mycoplasma bovis*, to the indication for use of tulathromycin solution in cattle, by subcutaneous injection, for the treatment of bovine respiratory disease. The application is approved as of August 18, 2006, and the regulations are amended in 21 CFR 522.2630 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 18, 2006.

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 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.

#### § 522.2630 [Amended]

■ 2. In § 522.2630, in paragraph (d)(1)(ii), remove "and *Histophilus somni* (*Haemophilus somnus*)" and add in its place "*Histophilus somni* (*Haemophilus somnus*), and *Mycoplasma bovis*".

Dated: September 15, 2006.

**Steven D. Vaughn,**

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

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## OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

### 29 CFR Part 2400

#### Regulations Implementing the Privacy Act of 1974

**AGENCY:** Occupational Safety and Health Review Commission.

**ACTION:** Final rule.

**SUMMARY:** The Occupational Safety and Health Review Commission (OSHRC) is amending its regulations implementing the Privacy Act of 1974, 5 U.S.C. 552a. The Privacy Act has been amended multiple times since OSHRC first promulgated its regulations in 1979. The amendments to OSHRC's regulations at 29 CFR Part 2400 will assist the agency in complying with the requirements of the Privacy Act.

**DATES:** Effective September 29, 2006.

**FOR FURTHER INFORMATION CONTACT:** Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606-5410, or via e-mail at [rbailey@oshrc.gov](mailto:rbailey@oshrc.gov).

**SUPPLEMENTARY INFORMATION:** OSHRC published a notice of proposed rulemaking on July 28, 2006, 71 FR 42785, which would revise 29 CFR Part 2400. Interested persons were afforded an opportunity to participate in the rulemaking process through submission of written comments on the proposed rule. OSHRC received no public comments. We have reviewed the proposed rule and now adopt it as the agency's final rule.

OSHRC's regulations at Part 2400 implementing the Privacy Act of 1974 were first promulgated on January 19, 1979, 44 FR 3968. These regulations had not been revised, except for changes made to the office address referenced in §§ 2400.6 and 2400.7, 58 FR 26065, April 30, 1993. Since 1979, however, the Privacy Act has been amended on numerous occasions. These statutory changes, along with intervening case law, compel OSHRC to amend its