DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Sterile Powder for Injection

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 Pharmacia and Upjohn Co. The supplemental NADA provides for intramuscular injection of a solution of reconstituted ceftiofur sodium powder for treatment of caprine respiratory disease (goat pneumonia).

DATES: This rule is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 140–338 that provides for use of Naxcel® (ceftiofur sodium) sterile powder for injection for treatment by intramuscular injection of caprine respiratory disease (goat pneumonia) associated with *Pasteurella haemolytica* and *P. multocida*.

The supplemental NADA is approved as of March 7, 2001, and the regulations are amended in 21 CFR 522.313 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 supplemental 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(d)(4) 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 FOR 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 522.313 is amended by revising the section heading and by adding paragraph (d)(8) to read as follows:

§ 522.313 Ceftiofur sodium powder for injection.

* * * * *

(d) * * *

(8) *Goats*—(i) *Amount.* 0.5 to 1.0 milligram per pound of body weight by intramuscular injection at 24-hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals that do not show satisfactory response.

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *Pasteurella haemolytica* and *P. multocida*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 16, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–10620 Filed 4–27–01; 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 new animal drug application (NADA) filed by Elanco Animal Health. The 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 prevention and/or control of porcine proliferative enteropathies (ileitis) in swine.

DATES: This rule is effective April 30, 2001.

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.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–172 that provides for use of Paylean® (9 grams per pound (g/lb) ractopamine hydrochloride) and Tylan® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated article to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness, and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis* in swine. The NADA is approved as of February 20, 2001, and the regulations are amended in 21 CFR 558.500 and 558.625 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)(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.