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.

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.

2. Section 558.500 is amended by revising paragraph (d)(1) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(d) *Conditions of use.*

(1) *Swine.*

Ractopamine in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.5		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness.	Feed continuously as sole ration. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(ii) 4.5 to 18		For improved feed efficiency and increased carcass leanness.	Feed continuously as sole ration. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(iii) 4.5	Tylosin 100	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*.	Feed continuously as sole ration for 21 days. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(iv) 4.5 to 18	Tylosin 100	For improved feed efficiency and increased carcass leanness; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.	Feed continuously as sole ration for 21 days. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986

* * * * *

3. Section 558.625 is amended by adding paragraph (f)(2)(vii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(vii) Ractopamine hydrochloride as in § 558.500.

Dated: April 16, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–10622 Filed 4–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD1–01–021]

RIN 2115–AA97

Safety Zone: McArdle Bridge Repairs—Boston, Massachusetts

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for repairs to the McArdle Bridge; during nine 3½ day closure periods between April 2, 2001 and September 21, 2001, in Boston, MA. The safety zone temporarily closes all waters of Boston Inner Harbor one hundred (100) yards upstream and downstream from the McArdle Bridge. The safety zone prohibits entry into or movement within this portion of Boston Inner Harbor during the closure periods without Captain of the Port authorization and is needed to allow The Middlesex Corporation (TMC) to conduct repairs on the McArdle Bridge.

DATES: This rule is effective from sunrise Monday, April 2 until sunset Friday, September 21, 2001.

ADDRESSES: Documents as indicated in this preamble are part of docket CGD01–01–21 and are available for inspection or copying at Marine Safety Office Boston, 455 Commercial Street, Boston, MA between the hours of 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) Dave Sherry, Marine Safety Office Boston, Waterways Management Division, at (617) 223–3006.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was published for this regulation on March 8, 2001 in 66 FR 13867, with the comment period ending March 15, 2001. Good cause exists for making this regulation effective in less than 30 days after **Federal Register** publication. Dates for this closure were not received by the Coast Guard until January 13, 2001. An NPRM was published with an abbreviated comment period with the intent of providing time for publication prior to the effective date of the regulation. The safety zone restricts movement within this portion of Boston Harbor and is needed to allow TMC to conduct repairs on the McArdle Bridge. The Captain of the Port anticipates minimal negative impact on vessel traffic due to this event. Notifications will be made prior to the effective period via safety marine information broadcasts, and local notice to mariners. Captain of the Port, Boston, will consider requests for passage through the zone of small vessels that can safely navigate the bridge during construction. If a request is granted, operators permitted to pass through the zone are requested to provide a four hour notice to the contractor at (617–