DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2010–N–0002]

Implantation and Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for veterinary prescription use of ceftiofur crystalline free acid suspension in swine, by intramuscular injection, for the control of swine respiratory disease (SRD) in groups of pigs where SRD has been diagnosed.

DATES: This rule is effective October 12, 2010.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141 235 for EXCEDE (ceftiofur crystalline free acid) for Swine Sterile Suspension. The supplemental NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in swine, by intramuscular injection, for the control of SRD associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis* in groups of pigs where SRD has been diagnosed. The application is approved as of September 15, 2010, and the regulations are amended in 21 CFR 522.313a to reflect the approval. In addition, the regulations are amended to specify which strength of two approved formulations is approved for use in horses. This is being done to improve the accuracy of the regulations.

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 approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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.

■ 2. In § 522.313a, add a second sentence to paragraph (e)(1)(ii) and revise paragraph (e)(3) to read as follows:

§ 522.313a Ceftiofur crystalline free acid.

* * * * *

(e) * * *

(1) * * *

(ii) * * * For the control of SRD associated with *A. pleuropneumoniae, P. multocida, H. parasuis,* and *S. suis* in groups of pigs where SRD has been diagnosed.

* * * * *

(3) *Horses.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus.*

(iii) *Limitations.* Do not use in horses intended for human consumption.

Dated: October 5, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–25527 Filed 10–8–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0861]

Drawbridge Operation Regulations; Saugatuck River, Saugatuck, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Saga Railroad Bridge across the Saugatuck River, mile 1.1, at Saugatuck, Connecticut. The deviation is necessary to facilitate scheduled rehabilitation maintenance at the bridge. Under this deviation the bridge may remain in the closed position from October 1, 2010 through October 17, 2010.

DATES: This deviation is effective with constructive notice from October 12, 2010 through October 17, 2010, and for enforcement with actual notice from October 1, 2010 through October 12, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0861 and are available online at *http://www.regulations.gov,* inserting USCG–2010–0861 in the "Keyword" and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Ms. Judy K. Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 668–7165, *judy.k.leung-yee@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.