Firm name and address	Drug labeler code
* * * * * * *	
BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	032761
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
032761	BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704
* * * * * * *	

Dated: May 28, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–17405 Filed 7–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride

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 injection of ceftiofur hydrochloride suspension in cattle for the treatment of acute metritis.

DATES: This rule is effective July 11, 2002.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7572, e-mail: cburnste@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplemental application to NADA 140–890 that provides for use of EXCENEL (ceftiofur hydrochloride) RTU Sterile Suspension by intramuscular or subcutaneous injection in cattle for the treatment of acute metritis (0 to 14 days post partum) associated with bacterial organisms susceptible to ceftiofur. The supplemental NADA is approved as of February 8, 2002, and the regulations are amended in § 522.314 (21 CFR 522.314) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 522.314 is also being revised to reflect a current format.

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.

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 application approval qualifies for 3 years of marketing exclusivity beginning February 8, 2002, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(5) 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. Section 522.314 is amended by revising the section heading, and paragraphs (a), (d)(1)(i), (d)(1)(iii), and (d)(2) to read as follows:

§ 522.314 Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

* * * * *

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

(2) *Cattle*—(i) *Dosage.* 1.1 to 2.2 mg/kg of body weight by intramuscular or subcutaneous injection, at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis, administer 2.2 mg/kg of body weight daily for 5 consecutive days.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* spp. (*Pasteurella haemolytica*), *P. multocida*, and *Haemophilus somnus*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with

Fusobacterium necrophorum and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations*. Do not slaughter treated cattle for 48 hours (2 days) after last treatment. A withdrawal period has not been established 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.

Dated: June 26, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–17404 Filed 7–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–02–038]

RIN 2115–AA97

Safety Zone; Lake Huron, Harbor Beach, MI

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Harbor Beach Fireworks on July 20, 21, 2002. This safety zone is necessary to control vessel traffic within the immediate location of the fireworks launch site and to ensure the safety of life and property during the event. This safety zone is intended to restrict vessel traffic from a portion of Lake Huron.

DATES: This temporary final rule is effective from 10 p.m. on July 20, 2002 until 11 p.m. on July 21, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket [CGD09–02–038] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Detroit, 110 Mt. Elliott Ave., Detroit, MI 48207, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Brandon Sullivan, U. S. Coast Guard Marine Safety Office Detroit, at (313) 568–9558.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments previously with regard to this event.

Background and Purpose

A temporary safety zone is necessary to ensure the safety of vessels and spectators from the hazards associated with fireworks displays. Based on recent accidents that have occurred in other Captain of the Port zones, and the explosive hazard of fireworks, the Captain of the Port Detroit has determined fireworks launches in close proximity to watercraft pose significant risks to public safety and property. The likely combination of large numbers of recreational vessels, congested waterways, darkness punctuated by bright flashes of light, alcohol use, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the launch platform will help ensure the safety of persons and property at these events and help minimize the associated risks.

The safety zone will encompass all waters of Lake Huron surrounding the fireworks launch platform bounded by the arc of a circle with a 300-yard radius with its center in approximate position 43°51′00″ N, 082°38′15″ W. The geographic coordinates are based upon North American Datum 1983 (NAD 83). The size of this zone was determined using the National Fire Prevention Association guidelines and local knowledge concerning wind, waves, and currents.

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol representative. Entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Detroit or his designated on-scene representative. The designated on-scene representative will be the Patrol Commander. The Patrol Commander may be contacted via VHF Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed this rule under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This determination is based on the minimal time that vessels will be restricted from the safety zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard considered whether this rule would have a significant impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of commercial vessels intending to transit or anchor in the activated safety zone.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: this safety zone is only in effect from 10 p.m. until 11 p.m. on the days of the event and vessel traffic is allowed to pass outside of the safety zone. Before the effective period, the Coast Guard will issue maritime advisories widely available to users of Lake Huron by the Ninth Coast Guard District Local Notice to Mariners and Marine Information Broadcasts. Facsimile broadcasts may also be made.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.