

Reporting

(c) Submit a report of the findings (both positive and negative) of the inspection required by paragraph (a) of this AD to Bombardier, Inc., Canadair, Aerospace Group, CRJ Technical Help Desk, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada; fax (514) 855-8501; at the applicable time specified in paragraph (c)(1) or (c)(2) of this AD. Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provision of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120-0056.

(1) If the inspection was done after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done prior to the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

Alternative Methods of Compliance

(d) In accordance with 14 CFR 39.19, the Manager, New York ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with Canadair Temporary Revision 2B-1566, dated January 31, 2003, to the Canadair Regional Jet Maintenance Requirements Manual, Part 2, Appendix B, "Airworthiness Limitations." This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF-2003-08, dated April 23, 2003.

Effective Date

(f) This amendment becomes effective on November 10, 2003.

Issued in Renton, Washington, on September 24, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 03-24679 Filed 10-3-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 529****Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts**

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 & Upjohn Co. The supplemental NADA provides for use of progesterone intravaginal inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

DATES: This rule is effective October 6, 2003.

FOR FURTHER INFORMATION CONTACT: Harlan J. Howard, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0231, e-mail: hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199 filed a supplement to NADA 141-200 that provides for use of EAZI-BREED CIDR Progesterone Intravaginal Inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus. The NADA is approved as of July 29, 2003, and the regulations are amended in 21 CFR 529.1940 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 Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning July 29, 2003.

The agency has determined under 21 CFR 25.33(c) 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 529

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 529.1940 is amended in paragraph (e)(3) in the first sentence by removing the phrase "or in lactating dairy cows"; and by revising paragraphs (d)(1), (d)(2), (e)(1), and (e)(2) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(d) * * *

(1) Product labeling shall bear the following warnings: "Avoid contact with skin by wearing latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed of in accordance with applicable local, State, and Federal regulations."

(2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(2)(i) of this section. See § 522.690(c) of this chapter.

* * * * *

(e) * * *

(1) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(2)(i) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.

(2) *Indications for use*—(i) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows,

and for advancement of first pubertal estrus in replacement beef heifers.

(ii) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

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Dated: September 24, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 03-25249 Filed 10-3-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07-03-131]

RIN 1625-AA09

Drawbridge Operation Regulations; St. Johns River, mile 24.7 at Jacksonville, Duval County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; change of effective date; request for comments.

SUMMARY: The Coast Guard is changing the effective dates for the temporary regulations governing the operation of the Main Street Bridge, mile 24.7, St. Johns River, Jacksonville, Florida. The contractor for the bridge repairs was unable to start work as scheduled in our temporary rule published on August 11, 2003. This change in effective dates is required to allow the bridge owner to begin the work on October 1, 2003 and complete the project by January 31, 2004.

DATES: This rule is effective from 6:01 a.m., October 30, 2003, until 6 a.m., January 31, 2004. Comments must be received by November 1, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [CGD07-03-131] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Room 432, Miami, FL 33131, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Project Officer, Seventh Coast Guard District, Bridge Branch, at (305) 415-6743.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting

comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07-03-131], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to confirm they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received. The Coast Guard may amend this temporary final rule based on comments received.

Regulatory Information

We 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. Publishing an NPRM was impracticable and contrary to the public interest, because the rule was needed to allow the contractor to provide for worker safety while repairing the bridge. Also, since the temporary rule provides for bridge openings during the majority of the day, during daytime hours when the area is most heavily traveled, vessel traffic will not be unduly disrupted during the repair process. A Temporary Rule was previously published as 68 FR 47462 which requested the same schedule changes but occurring on different dates. The contractor contacted the Coast Guard on August 11, 2003 and requested the date change due to delays in obtaining materials.

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 **Federal Register** publication. Though the contractor submitted a letter on May 29, 2003, requesting a change to the bridge's operating schedule to effect repairs, that request was incorrectly addressed and did not reach the Seventh Coast Guard Bridge Branch until faxed there on July 7, 2003. Accordingly, there was insufficient time remaining to either publish an NPRM or delay the effective date of the rule. This temporary rule provides for a reduction in bridge openings so as to allow the contractor to safely repair the bridge while providing for the reasonable needs of navigation during daylight hours.

Background and Purpose

The Main Street Bridge, mile 24.7, St. Johns River at Jacksonville, Duval County, Florida, has a vertical clearance of 40 feet at mean high water and a

horizontal clearance of 350 feet between the fender systems. The existing operating regulation in 33 CFR 117.325 (a) requires the bridge to open on signal except that, from 7 a.m. to 8:30 a.m. and 4:30 p.m. to 6 p.m., Monday through Saturday, except Federal holidays, the draw need not open for the passage of vessels. The draw opens at any time for vessels in an emergency involving life or property.

Royal Bridge, Inc., contractors, notified the Coast Guard on July 7, 2003, that work on the vertical lift bridge was scheduled from August 18, 2003, to October 31, 2003 and we published a temporary rule (68 FR 47462, August 11, 2003) to change the bridge operating schedule to accommodate the work. On August 11, 2003 the contractor again contacted the Coast Guard and requested the same operating schedule for a different time period, October 1, 2003 until January 31, 2004. The new work period is a month and a half longer than the original work period to allow for additional holidays and winter weather delays. For worker safety reasons, there will be a 5-foot reduction in vertical clearance, due to scaffolding. This temporary rule is necessary to provide for worker safety during repairs to the bridge and does not significantly hinder navigation, as openings will be provided throughout the remainder of the day.

Discussion of Rule

Under this temporary rule, the bridge need not open from 8 p.m. until 6 a.m., October 1, 2003, to January 31, 2004. This action is necessary for worker safety during repairs to the bridge and does not significantly hinder navigation.

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 it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The temporary rule will impact vessels of greater than 35 feet in height because of the reduction in vertical clearance. The temporary rule, however, will only affect a small percentage of vessel traffic through the bridge, because of limited nighttime navigation at this location and