

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]

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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,