DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

[Docket No. FDA–2010–N–0002]

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., a Division of Pfizer, Inc. The supplemental NADA provides for use of progesterone intravaginal inserts and dinoprost tromethamine by injection for synchronization of estrus in lactating dairy cows.

DATES: This rule is effective October 14, 2010.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish PL, Rockville, MD 20855, 240–276–8105, e-mail: suzanne.sechen@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 141–200 that provides for use of EZAI–BREED CIDR Progesterone Intravaginal Inserts and dinoprost tromethamine by injection for synchronization of estrus in lactating dairy cows. The NADA is approved as of July 22, 2010, and the regulations are amended in 21 CFR 529.1940 to reflect the approval.

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 supplemental 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 529

Animal drugs.

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


2. In § 529.1940, revise paragraphs (d)(2) and (e)(1) and remove the last sentence in paragraph (e)(2)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(d) * * *

(2) Cows. This product is approved with the concurrent use of dinoprost solution when used for indications listed in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section. See § 522.690(c) of this chapter.

(e) * * *

(1) Cows—(i) Amount. Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) 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 1 day prior to insert removal (Day 6). When used for indications listed in paragraph (e)(1)(ii)(B) of this section, administer 25 mg dinoprost as a single intramuscular injection on the day of insert removal (Day 7).

(ii) Indications for use—(A) 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.

(B) For synchronization of estrus in lactating dairy cows.

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

(iii) Limitations. Do not use in beef or dairy heifers of insufficient size or age for breeding or in animals with abnormal, immature, or infected genital tracts. Do not use in beef cows that are fewer than 20 days postpartum. Do not use an insert more than once. To prevent the transmission of venereal and bloodborne diseases, the inserts should be disposed of after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprostone solution provided by No. 000009 in § 510.600(c) of this chapter.

Supplementary Information:
The City of Duluth, MN, who owns and operates this drawbridge, has requested a temporary deviation from the current operating regulations set forth in 33 CFR 117.661. The purpose of this request is to facilitate structural maintenance of the bridge superstructure. The bridge is normally required to open at least 24 hours advance notice is provided during the scheduled maintenance period. Vessels that can pass under the bridge without an opening may do so at any time. The bridge has a horizontal clearance of 300 feet and a vertical clearance of 15 feet in the closed position. Mariners that require passage between the harbor and Lake Superior with an air draft greater than 15 feet may use the Superior Entrance Channel, Superior, Wisconsin at any time. Impact to masted navigation is mitigated by the close proximity of an alternate route and the reduced navigational needs in the harbor during the winter. The most updated and detailed marine information for this event, and all bridge operations, is found in the Local Notice to Mariners and Broadcast Notice to Mariners issued by the Coast Guard. From 6 a.m. on January 14, 2011 to 10 a.m. on March 14, 2011 the bridge need not open for any vessel. In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.


Scot M. Striffer,
Bridge Program Manager, Ninth Coast Guard District.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0912]

Drawbridge Operation Regulations; Duluth Ship Canal (Duluth-Superior Harbor).

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: Commander, Ninth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Duluth Ship Canal Aerial Bridge at Mile 0.1 over the Duluth Ship Canal, at Duluth, MN, for scheduled maintenance. During this temporary deviation the bridge will be secured to masted navigation. Vessels that can pass under the bridge without an opening may do so at any time.

DATES: This deviation is effective from 6 a.m. on January 14, 2011 to 10 a.m. on March 14, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0912 and are available online by going to http://www.regulations.gov, inserting USCG–2010–0912 in the “Keyword” box 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 temporary rule, call or e-mail Lieutenant Junior Grade Jason Erickson, Coast Guard; telephone 901–521–4753, e-mail Jason.A.Erickson@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: