

following information with respect to the swap transaction:

(i) A copy of the transaction confirmation, in electronic form if available, or in written form if there is no electronic copy; and

(ii) The time, if available, that the transaction was executed; and

(2) Report to the Commission on request, in a form and manner prescribed by the Commission, any information relating to the swap transaction.

Note to Paragraphs (a)(1) and (a)(2). In order to comply with the reporting requirements contained in paragraph (a)(1) and (a)(2) of this section, each counterparty to a pre-enactment unexpired swap transaction that may be required to report such transaction should retain, in its existing format, all information and documents, to the extent and in such form as they presently exist, relating to the terms of a swap transaction, including but not limited to any information necessary to identify and value the transaction; the date and time of execution of the transaction; information relevant to the price of the transaction; whether the transaction was accepted for clearing and, if so, the identity of such clearing organization; any modification(s) to the terms of the transaction; and the final confirmation of the transaction.

(b) *Reporting party.* The counterparties to a swap transaction shall report the information required under paragraph (a) of this section as follows:

(1) Where only one counterparty to a swap transaction is a swap dealer or a major swap participant, the swap dealer or major swap participant shall report the transaction;

(2) Where one counterparty to a swap transaction is a swap dealer and the other counterparty is a major swap participant, the swap dealer shall report the transaction; and

(3) Where neither counterparty to a swap transaction is a swap dealer or a major swap participant, the counterparties to the transaction shall select the counterparty who will report the transaction.

By the Commission.

Dated: October 1, 2010.

**David A. Stawick,**

*Secretary.*

[FR Doc. 2010-25325 Filed 10-13-10; 8:45 am]

**BILLING CODE 6351-01-P**

## 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](mailto: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 EAZI-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.

■ 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. 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 potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution provided by No. 000009 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: October 8, 2010.

**Steven D. Vaughn,**

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

[FR Doc. 2010-25893 Filed 10-13-10; 8:45 am]

**BILLING CODE 4160-01-P**

## 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 rule, call or e-mail Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216-902-6085, e-mail; [lee.d.soule@uscg.mil](mailto:lee.d.soule@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**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 if 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.

Dated: September 28, 2010.

**Scot M. Striffler,**

*Bridge Program Manager, Ninth Coast Guard District.*

[FR Doc. 2010-25805 Filed 10-13-10; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2010-0873]

RIN 1625-AA00

#### **Great Mississippi Balloon Race and Fireworks Safety Zone; Lower Mississippi River, Mile Marker 365.5 to Mile Marker 363, Natchez, MS**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for all waters of the Lower Mississippi River from mile marker 365.5 to 363 extending the entire width of the river. This safety zone is needed to protect persons and vessels from the potential safety hazards associated with a fireworks display and low flying hot air balloons transiting across the Lower Mississippi River. Entry into this zone is prohibited to all vessels, mariners, and persons unless specifically authorized by the Captain of the Port (COTP) Lower Mississippi River or a designated representative. The COTP Lower Mississippi River or a designated representative must authorize vessels that desire to operate in this zone.

**DATES:** This rule is effective from 7:15 p.m. on October 15, 2010, until 6 p.m. on October 16, 2010.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0873 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0873 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](mailto: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:**