(purchases only); other trade-related services; performing arts, sports, and other live performances, presentations, and events; primary insurance premiums (payments only); primary insurance losses recovered; sale or purchase of rights to natural resources, and lease bonus payments; use or lease of rights to natural resources, excluding lease bonus payments; waste treatment and depollution services; and other private services (language translation services; salvage services; security services; account collection services; satellite photography and remote sensing/satellite imagery services; space transport (includes satellite launches, transport of goods and people for scientific experiments, and space passenger transport); and transcription services).

* * * * *

[FR Doc. 05–16305 Filed 8–16–05; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's address for Peptech Animal Health Pty, Ltd.

DATES: This rule is effective August 17, 2005.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia has informed FDA of a change of address to 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Peptech Animal Health Pty, Ltd.''; and in the table in paragraph (c)(2) by revising the entry for ''064288'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Peptech Animal Health Pty, Ltd., 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia.	064288
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
064288	Peptech Animal Health Pty, Ltd., 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia
* * * * *	

July 28, 2005.

Bernadette A. Dunham,

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

[FR Doc. 05–16280 Filed 8–16–05; 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; Phenylbutazone Injection

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 an abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for the veterinary prescription use of phenylbutazone injectable solution in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective August 17, 2005.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9808, e-mail: *john.harshman@fda.gov*.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa , KS 66215–3591, filed ANADA 200–371 for the use of Phenylbutazone 20% Injection by veterinary prescription for relief of inflammatory conditions associated with the musculoskeletal system in horses. Sparhawk Laboratories, Inc.'s, Phenylbutazone 20% Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s, BUTAZOLIDIN Injectable 20%, approved under NADA 11–575. The ANADA is approved as of July 8, 2005, and the regulations in 21 CFR 522.1720 are amended to reflect the approval. The basis of approval is discussed in the freedom of information(FOI) summary.

In accordance with the FOI 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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

§ 522.1720 [Amended]

■ 2. Section 522.1720 is amended in paragraph (b)(2) by removing ''No. 000010'' and by adding in its place ''Nos. 000010 and 058005''.

Dated: July 26, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–16240 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–040]

RIN 1625–AA09

Drawbridge Operation Regulation; Massalina Bayou, Panama City, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary rule.

SUMMARY: The Commander, Eighth Coast Guard District, has temporarily changed the regulation governing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, at Panama City, Bay County, Florida. The regulation will allow the draw of the bridge to remain closed to navigation for one hour to facilitate the American Heart Walk.

DATES: This temporary rule is effective from 9 a.m. to 10 a.m. on October 15, 2005.

ADDRESSES: Documents referred to in this rule are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, 500 Poydras Street, New Orleans, Louisiana 70130–3310, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Eighth District Bridge Administration Branch maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, (504) 589–2965.

SUPPLEMENTARY INFORMATION:

Good Cause for Not Publishing an NPRM

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. Thousands of pedestrians will cross the bridge during the event and this temporary rule is necessary to ensure their safety as they cross the bridge. Additionally, the event will only impact the waterway users for one hour and will open for vessels in distress.

Background and Purpose

The American Heart Association, on behalf of the City of Panama City, has requested a temporary rule changing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, in Panama City, Bay County, Florida. This temporary rule is needed to accommodate approximately 2,000 pedestrians that are expected to participate in a 3.5-mile walk. The bridge is near the beginning of the walk and allowing the bridge to open for navigation during this short time period would disrupt the event and could result in injury. The bridge has a vertical clearance of 7 feet above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists primarily of commercial fishing vessels, sailing vessels and other recreational craft. Presently, Title 33, Code of Federal Regulations (CFR), Part 117.301 states: The draw of the Tarpon Dock bascule span bridge, Massalina Bayou, mile 0.0, shall open on signal; except that from 9 p.m. until 11 p.m. on July 4, each year, the draw need not open for the passage of vessels. The draw will open at any time for a vessel in distress. This temporary rule will allow the bridge to be maintained in the closed-to-navigation position from 9 a.m. to 10 a.m. on October 15, 2005 to facilitate the American Heart Walk.

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). This temporary rule will be effective for only one hour and is therefore expected to have only a minor affect on the local economy.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic 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 temporary rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit through the Tarpon dock bridge across Massalina Bayou during the closure. There is not expected to be a significant impact due to the short duration of the closure and the publicity given to the event.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by