Collegeville, PA, Perkiomen Valley, RNAV (GPS) RWY 9, Amdt 1
Du Bois, PA, Du Bois-Jefferson County, RNAV (GPS) RWY 7, Orig
Du Bois, PA, Du Bois-Jefferson County, VOR/DME RNAV OR GPS RWY 7, Amdt 1, CANCELLED
Du Bois, PA, Du Bois-Jefferson County, Takeoff Minimums and Obstacle DP, Orig
Cotulla, TX, Cotulla-La Salle County, VOR–A, Amdt 13
Cotulla, TX, Cotulla-La Salle County, Takeoff Minimums and Obstacle DP, Orig
Farmville, VA, Farmville Regional, Takeoff Minimums and Obstacle DP, Orig
Huntington, WV, Tri-State/Milton J. Ferguson Field, ILS OR LOC RWY 12, Amdt 12
Huntington, WV, Tri-State/Milton J. Ferguson Field, ILS OR LOC RWY 30, Amdt 5
Huntington, WV, Tri-State/Milton J. Ferguson Field, RNAV (GPS) RWY 12, Amdt 1
Huntington, WV, Tri-State/Milton J. Ferguson Field, RADAR–1, Amdt 6
Huntington, WV, Tri-State/Milton J. Ferguson Field, Takeoff Minimums and Obstacle DP, Orig

[FR Doc. E7–19240 Filed 10–4–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Polysulfated Glycosaminoglycan

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 Luitpold Pharmaceuticals, Inc. The supplemental NADA provides for a revised food safety warning on labeling for an injectable solution of polysulfated glycosaminoglycan used in horses.

DATES: This rule is effective October 5, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, filed a supplement to NADA 140–901 for ADEQUAN i.m. (polysulfated glycosaminoglycan), an injectable solution approved for use in horses and dogs by veterinary prescription for noninfectious degenerative and/or traumatic joint disease. The supplemental NADA provides for a revised food safety warning for use in horses. The application is approved as of September 10, 2007, and the regulations are amended in 21 CFR 522.1850 to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under § 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 Parts 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.

■ 2. Revise § 522.1850 to read as follows:

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications*. Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan; each 5-mL ampule or vial contains 500 mg polysulfated glycosaminoglycan.

(b) *Sponsor*. See No. 010797 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Indications for use*. For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount*—(A) *Intra-articular use (carpal)*: 250 mg once a week for 5 weeks.

(B) *Intramuscular use (carpal and hock)*: 500 mg every 4 days for 28 days.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(2) *Dogs*—(i) *Indications for use*. For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount*. 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

Dated: September 26, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–19729 Filed 10–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; Ractopamine

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 Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter, a revision to bacterial pathogen nomenclature, and an increase in liver tolerance.

DATES: This rule is effective October 5, 2007.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0221, e-mail: *suzanne.sechen@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–233 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), RUMENSIN (monensin), and TYLAN (tylosin phosphate) Type A medicated articles to

make dry and liquid four-way combination Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for suppression of estrus (heat); and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The supplemental NADA provides for an increased level of monensin in four-way combination Type C medicated feeds containing ractopamine, melengestrol, monensin, and tylosin for heifers fed in confinement for slaughter, a revision to bacterial pathogen nomenclature, and an increase in the cattle liver tolerance. The supplemental NADA is approved as of September 11, 2007, and the regulations in 21 CFR 556.420 and 558.500 are amended 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.

The agency has determined under 21 CFR 25.33(a)(2) 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

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. In § 556.420, revise paragraph (b)(1) to read as follows:

§ 556.420 Monensin.

* * * * *

(b) * * *

(1) *Cattle*—(i) *Liver*. 0.10 part per million (ppm).

(ii) *Muscle, kidney, and fat*. 0.05 ppm.

(iii) *Milk*. Not required.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. In § 558.500, in the table in paragraph (e)(2), revise paragraph (e)(2)(x) and add paragraph (e)(2)(xi) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* * *	*	*
(x) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see paragraphs §§ 558.342(d), 558.355(d) and 558.625(c) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986
(xi) 9.8 to 24.6	Monensin 10 to 30, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/ head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see paragraphs §§ 558.342(d), 558.355(d) and 558.625(c) of this chapter. Melengestrol acetate as provided by No. 021641 in § 510.600(c) of this chapter.	021641

Dated: September 26, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–19732 Filed 10–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. CGD08–07–022]

Drawbridge Operation Regulations; Milhomme Bayou, Stephensville, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Stephensville Bridge across Milhomme Bayou, mile 12.2, at Stephensville, St. Martin Parish, Louisiana. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The deviation will allow the draw of the Stephensville Bridge to open on signal if at least one hour of advance notice is given. During the advance notice period, the draw shall open on less than one hour notice for an emergency and shall open on demand should a temporary surge in waterway traffic occur.

DATES: This deviation is effective from October 5, 2007 until April 2, 2008.

ADDRESSES: You may mail comments and related material to Commander (dpb), Eighth Coast Guard District, 500 Poydras Street, New Orleans, Louisiana 70130–3310. The Commander, Eighth Coast Guard District, Bridge Administration Branch maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the Bridge Administration office between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bart Marcules, Bridge Administration Branch, telephone (504) 671–2128.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in evaluating this test schedule by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this deviation [CGD08–07–022], 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 8 by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. Comments must be received by December 4, 2007.

Background and Purpose

St. Martin Parish has requested that the operating regulation on the Stephensville Bridge be changed in order to operate the bridge more efficiently. The Stephensville Bridge is located on Milhomme Bayou at mile 12.2 in Stephensville, St. Martin Parish, Louisiana. The Bridge has a vertical clearance of 5.8 feet above mean high water, an elevation of 3.5 feet Mean Sea Level (MSL) in the closed position and unlimited in the open position. The Stephensville Bridge opens on signal as required by 33 CFR 117.5. This operating schedule has been in effect since 2002 when this bridge replaced an existing bridge in the area.

The previous bridge's operating schedule was, ''shall open on signal; except that, from 10 p.m. to 6 a.m. the draw shall open on signal if at least two hours notice is given. During the advance notice period, the draw shall open on less than two hours notice for an emergency and shall open on demand should a temporary surge in waterway traffic occur.''

Since the completion of the current bridge, the waterway traffic has been minimal and during the past twelve months an average of 5 boats per day have requested an opening. Most of the boats requesting openings are commercial vessels consisting of tugboats with barges and shrimp trawlers that routinely transit this waterway and are able to give advance notice.

Due to this waterway being a secondary route, the Port Allen Alternate route is the primary route, little impact is expected on navigation during this test schedule period. Also, prior coordination with the main waterway user group in the area indicates no expected impacts.

A Notice of Proposed Rule Making [CGD08–07–023], is being issued in conjunction with this Temporary Deviation to obtain public comments. The Coast Guard will evaluate public comments from this Temporary Deviation and the above referenced Notice of Proposed Rule Making to determine if a permanent special drawbridge operating regulation is warranted.

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 21, 2007.

David M. Frank,

Bridge Administrator.

[FR Doc. 07–4860 Filed 10–4–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP LA–LB 07–004]

RIN 1625–AA00

Safety Zone; Queensway Bay, Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the Long Beach Harbor to encompass the waters between Queensway Bay to Island White at Long Beach harbor for the Annual Los Angeles and Long Beach Tug Boat Race. This safety zone is needed to prevent vessels from transiting the area during the race in order to protect vessels and personnel from potential damage and injury. Entry into this safety zone will be prohibited unless specifically authorized by the Captain of the Port, Los Angeles-Long Beach, or his on-scene representative.

DATES: This rule is effective from 5 p.m. to 7 p.m. on September 27, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket COTP LA–LB 07–004 and are available for inspection or copying at Sector Los Angeles—Long Beach, 1001 S. Seaside Ave, San Pedro, CA 90731 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Peter Gooding,