

During the selection of these materials, consideration must also be given to ensure that the flammability characteristics of the materials will not be adversely affected by the use of cleaning agents and utensils used to remove cooking stains.

b. Retain the surface materials of the existing galleys surrounding the cooktops per the airworthiness approval of the Boeing 747-2G4B model aircraft flammability requirements of Part I (§ 25.853 Amendment 25-59) of Appendix F of part 25. The use of the existing flammability approvals of the galley per the Type Certificate (A20WE) certification basis for the Boeing 747-2G4B model is acceptable as this modification consists of structural changes strictly to accommodate the installation of new cooktops.

6. The cooktop must be ventilated with a system independent of the airplane cabin and cargo ventilation system. Procedures and time intervals must be established to inspect and clean or replace the ventilation system to prevent a fire hazard from the accumulation of flammable oils and be included in the instructions for continued airworthiness. The ventilation system ducting must be protected by a flame arrestor or an automatic shutoff valve in the over-range top ventilation system in lieu of the flame arrestor. [Note: The applicant may find additional useful information in Society of Automotive Engineers, Aerospace Recommended Practice 85, Rev. E, entitled "Air Conditioning Systems for Subsonic Airplanes," dated August 1, 1991.]

7. Means must be provided to contain spilled foods or fluids in a manner that will prevent the creation of a slipping hazard to occupants and will not lead to the loss of structural strength due to corrosion.

8. Cooktop installations must provide adequate space for the user to immediately escape a hazardous cooktop condition.

9. A means to shut off power to the cooktop must be provided at the galley containing the cooktop and in the cockpit. If additional switches are introduced in the cockpit, revisions to smoke or fire emergency procedures of the AFM will be required.

Issued in Renton, Washington, on March 22, 2011.

K.C. Yanamura,

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011-7343 Filed 3-28-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 526, and 529

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Amikacin Sulfate, Ampicillin Trihydrate, Ceftiofur Hydrochloride, Cephapirin Benzathine, Chlortetracycline, Fenbendazole, Formalin, Furosemide, Glucose/Glycine/Electrolyte, Pyrantel Pamoate, Sulfadimethoxine, Sulfamethazine, and Tetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect revised human food safety warnings or updated pathogen nomenclature on dosage form new animal drug product labeling that have not been codified. The regulations are also being amended to correct the wording of certain other conditions of use, to correct minor errors, and to revise some sections to reflect a current format. These actions are being taken to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to improve the accuracy and readability of the regulations. **DATES:** This rule is effective March 29, 2011.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not reflect certain human food safety warnings or the scientific nomenclature of pathogens that have been updated on labeling of various dosage form new animal drug products. At this time, the regulations are being amended to reflect approved labeling. The regulations are also being amended to correct the wording of certain other conditions of use and to correct minor errors. As the opportunity has presented itself, some sections have been revised to a current format. These actions are being taken to comply with the FD&C Act and to improve the accuracy and readability of the regulations.

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 520, 522, 526, and 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 parts 520, 522, 526, and 529 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.550, revise the section heading and paragraph (a), the first sentence in paragraph (c)(1), and paragraph (c)(3) to read as follows:

§ 520.550 Glucose/glycine/electrolyte.

(a) *Specifications.* The product is distributed in packets each of which contains the following ingredients: Sodium chloride 8.82 grams, potassium phosphate 4.20 grams, citric acid anhydrous 0.5 gram, potassium citrate 0.12 gram, aminoacetic acid (glycine) 6.36 grams, and glucose 44.0 grams.

(c) * * *

(1) Glucose/glycine/electrolyte is indicated for use in the control of dehydration associated with diarrhea (scours) in calves. * * *

* * * * *

(3) The product should not be used in animals with severe dehydration (down, comatose, or in a state of shock). Such animals need intravenous therapy. A veterinarian should be consulted in severely scouring calves. The product is not nutritionally complete if administered by itself for long periods of time. It should not be administered beyond the recommended treatment period without the addition of milk or milk replacer.

■ 3. In § 520.905a, revise paragraphs (e)(2)(i), (e)(2)(iii), (e)(3)(i), and (e)(3)(iii) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

* * * * *

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not

been established for this product in prerinuating calves. Do not use in calves to be processed for veal.

(3) * * *

(i) *Amount.* Administer orally 10 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

* * * * *

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 4. In § 520.905c, revise paragraph (e)(2)(iii) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal.

■ 5. In § 520.1422, revise paragraph (b) to read as follows:

§ 520.1422 Metoserpate hydrochloride.

* * * * *

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

* * * * *

■ 6. In § 520.2043, revise paragraph (d)(1)(iii) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Do not use in horses intended for human consumption. When the drug is for administration by stomach tube, it shall be labeled: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

* * * * *

■ 7. In § 520.2044, revise paragraph (d)(2) to read as follows:

§ 520.2044 Pyrantel pamoate paste.

* * * * *

(d) * * *

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

■ 8. In § 520.2220a, revise paragraph (d)(3)(ii) to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

* * * * *

(d) * * *

(3) * * *

(ii) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

* * * * *

■ 9. In § 520.2220b, revise paragraph (d) to read as follows:

§ 520.2220b Sulfadimethoxine tablets and boluses.

* * * * *

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat for 4 to 5 days.

(ii) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations.* Do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal.

(2) *Dogs and cats*—(i) *Amount.* Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours.

(ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

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

(3) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.

(ii) *Indications for use.* Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella* spp. sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older.

Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 10. In § 520.2260a, revise paragraph (a)(3)(iii) to read as follows:

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a) * * *

(3) * * *

(iii) *Limitations.* Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Do not treat cattle within 10 days of slaughter. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in prerinuating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption.

* * * * *

■ 11. In § 520.2261a, revise the section heading; the first sentence in paragraph (c)(2)(iii); and paragraph (c)(3) to read as follows:

§ 520.2261a Sulfamethazine solution.

* * * * *

(c) * * *

(2) * * *

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). * * *

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or

older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in prerinuating calves. Do not use in calves to be processed for veal.

* * * * *

■ 12. In § 520.2261b, revise paragraph (d)(1)(ii) and paragraph (d)(4)(iii) to read as follows:

§ 520.2261b Sulfamethazine powder.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *E. necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*).

* * * * *

(4) * * *

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle 10 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated cattle must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in prerinuating calves. Do not use in calves to be processed for veal.

■ 13. In § 520.2345d, revise paragraph (b)(2), the first sentence in paragraph (d)(1)(iii), and paragraph (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

* * * * *

(b) * * *

(2) No. 000010: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 000010 and within 5 days of treatment for Nos. 046573, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. * * *

(2) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No.

000010 and within 4 days of treatment for Nos. 046573, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 14. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 15. Revise § 522.56 to read as follows:

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 16. In § 522.90b, revise the section heading and paragraphs (a), (b), and (d) to read as follows:

§ 522.90b Ampicillin trihydrate.

(a) *Specifications.* Each milliliter of aqueous suspension constituted from ampicillin trihydrate powder contains 50, 100, or 250 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 000010 and 010515 in § 510.600(c) of this chapter.

* * * * *

(d) *Conditions of use—(1) Dogs and cats—(i) Amount.* 3 mg/pound (lb) of body weight twice daily by subcutaneous or intramuscular injection.

(ii) *Indications for use.* For treatment of strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

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

(2) *Cattle—(i) Amount.* 2 to 5 mg/lb of body weight once daily by intramuscular injection.

(ii) *Indications for use.* For treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, and *Escherichia coli*.

(iii) *Limitations.* Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment or for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment or for 144 hours (6 days) after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 17. In § 522.313b, revise paragraph (a) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

* * * * *

■ 18. In § 522.1010, redesignate paragraph (d)(3)(iii) as paragraph (d)(2)(iii); and add new paragraph (d)(3)(iii) to read as follows:

§ 522.1010 Furosemide.

* * * * *

(d) * * *

(3) * * *

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 19. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 20. In § 526.363, revise paragraph (d)(1) and the first sentence in paragraph (d)(3) to read as follows:

§ 526.363 Cephapirin benzathine.

* * * * *

(d) * * *

(1) *Amount.* Infuse the contents of one syringe into each quarter.

* * * * *

(3) *Limitations.* Infuse each quarter following last milking, but no later than 30 days before calving. * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.50 [Redesignated as § 529.56 and Amended]

■ 22. Redesignate § 529.50 as § 529.56 and revise it to read as follows:

§ 529.56 Amikacin.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 23. In § 529.1030, revise paragraphs (d)(1)(i) and (d)(1)(iv) to read as follows:

§ 529.1030 Formalin.

* * * * *

(d) * * *

(1) * * *

(i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyru* spp., on salmon, trout, catfish, largemouth bass, and bluegill.

* * * * *

(iv) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyru* spp.

* * * * *

Dated: March 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-7313 Filed 3-28-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG-2009-0996]

RIN 1625-AA08

Special Local Regulation; Hydroplane Races Within the Captain of the Port Puget Sound Area of Responsibility

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a special local regulation to restrict vessel movement in designated permanent hydroplane race areas in Dyes Inlet, Lake Washington and Lake Sammamish, WA during permitted hydroplane race events. When this special local regulation is activated, and thus subject to enforcement, this rule will limit the movement of non-participating vessels within the regulated race areas immediately prior to, during and immediately following the conclusion of permitted hydroplane marine events. This rule is needed to provide effective control over these events while ensuring the safety of the maritime public.

DATES: This rule is effective March 29, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0996 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0996 in the "Keyword" box, and then clicking "Search." This material is 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 LTJG Ashley M. Wanzer, Waterways Management, Sector Puget Sound, Coast Guard; telephone 206-217-6175, e-mail SectorPugetSoundWWM@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On Tuesday, January 19, 2010, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone Regulation; Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility in the **Federal Register** (75 FR 2833). On Wednesday, January 19, 2011, we published a supplemental notice of proposed rulemaking (SNPRM), revising the rulemaking to create a special local regulation designating three permanent hydroplane race areas under 33 CFR part 100 in the **Federal Register** (76 FR 3057). We did not receive any comments on the NPRM or SNPRM and did not receive any requests for a public meeting. A public meeting was not held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Immediate action is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the intended objective of promoting safety during these permitted events because the ULHRA Spring Training takes place on 21 April 2011 in the Lake Washington designated race area and this is less than 30 days after publication in the **Federal Register**.

Basis and Purpose

The U.S. Coast Guard is establishing special local regulations to establish three permanent designated hydroplane race areas in Dyes Inlet, Lake Washington, and Lake Sammamish, WA within the Captain of the Port, Puget Sound Area of Responsibility. This action is necessary in order to restrict vessel movement in the vicinity of the race courses thereby promoting safety on navigable waters during these events.

Background

The Coast Guard receives numerous marine event permits for hydroplane races taking place on the waterways of Dyes Inlet, Lake Washington, and Lake Sammamish, WA. This rule establishes a special local regulation to restrict vessel movement in designated hydroplane race areas during permitted hydroplane marine events. This rule enables event sponsors and the Coast Guard to adequately provide safety in support of these marine events.

Initial Enforcement

The Coast Guard will enforce the special local regulation for Lake Washington in 33 CFR 100.1308 from 10 a.m. until 4 p.m. on April 21, 2011.