

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it creates additional controlled airspace at Shelby Airport, Shelby, MT.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Shelby, MT [Modified]

Shelby Airport, MT
(Lat. 48°32′26″ N., long. 111°52′16″ W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Shelby Airport, and within 2.7 miles each side of the 043° bearing from Shelby Airport extending from the 6.7-mile radius to 7.4 miles northeast of the airport; that airspace extending upward from 1,200 feet above the surface within an area bounded by lat. 48°50′00″ N., long. 111°45′00″ W.; to lat. 48°49′00″ N., long. 111°22′00″ W.; to lat. 48°38′00″ N., long. 111°17′00″ W.; to lat. 48°21′00″ N., long. 111°36′00″ W.; to lat. 48°18′00″ N., long. 112°01′00″ W.; to lat. 48°28′00″ N., long. 112°12′00″ W.; to lat. 48°38′00″ N., long. 112°11′00″ W.; to lat. 48°38′00″ N., long. 112°03′00″ W., thence to the point of beginning.

Issued in Seattle, Washington, on August 15, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–21648 Filed 8–24–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

[Docket No. FDA–2011–N–0003]

New Animal Drugs; Ampicillin Trihydrate, Bacitracin Methylene Disalicylate, Flunixin, Gonadotropin Releasing Factor Analog-Diphtheria Toxoid Conjugate, Methylprednisolone, and Sulfamethazine

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 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 (the FD&C Act) and to improve the

accuracy and readability of the regulations.

DATES: This rule is effective August 25, 2011.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not reflect certain human food safety warnings 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 and 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 parts 520 and 522 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 § 520.154a, revise the section heading and paragraphs (d)(1)(i), (d)(2)(i), (d)(2)(ii), (d)(2)(ii)(A), and (d)(4)(i) to read as follows:

§ 520.154a Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 400 milligrams (mg) per gallon (gal) in drinking water.

* * * * *

(2) * * *

(i) *Amount.* 100 mg per gal in drinking water.

* * * * *

(ii) *Amount*. 200 to 400 mg per gal in drinking water. Administer continuously 5 to 7 days or as long as clinical signs persist, then reduce to prevention levels (100 mg/gal).

(A) *Indications for use*. Treatment of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

* * * * *

(4) * * *

(i) *Amount*. 400 mg per gal in drinking water.

* * * * *

■ 3. Revise § 520.970 to read as follows:

§ 520.970 Flunixin.

(a) *Specifications*. (1) Each 10-gram (g) packet of granules contains flunixin meglumine equivalent to 250 milligrams (mg) of flunixin.

(2) Each 30-g syringe of paste contains flunixin meglumine equivalent to 1,500 mg of flunixin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.5 mg of flunixin per pound of body weight per day.

(2) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders.

(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.

§ 520.970a [Removed]

■ 4. Remove § 520.970a.

§ 520.970b [Removed]

■ 5. Remove § 520.970b.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 7. In § 522.90b, revise paragraph (d)(2)(iii) to read as follows:

§ 522.90b Ampicillin trihydrate.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations*. Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and 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.

■ 8. In § 522.1083, revise the section heading and paragraph (a) to read as follows:

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(a) *Specifications*. Each milliliter of solution contains 0.2 milligrams (mg) gonadotropin releasing factor analog-diphtheria toxoid conjugate.

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■ 9. In § 522.1410, revise the section heading, remove and reserve paragraph (c), and revise paragraphs (a) and (d) to read as follows:

§ 522.1410 Methylprednisolone.

(a) *Specifications*. Each milliliter of suspension contains 20 or 40 milligrams (mg) of methylprednisolone acetate.

(b) * * *

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 2 to 40 mg (up to 120 mg in extremely large breeds or dogs with severe involvement) by intramuscular injection or up to 20 mg by intrasynovial injection.

(ii) *Indications for use*. For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

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

(2) *Cats*—(i) *Amount*. Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use*. For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

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

(3) *Horses*—(i) *Amount*. Administer 200 mg by intramuscular injection or 40 to 240 mg by intrasynovial injection.

(ii) *Indications for use*. For treatment of inflammation and related disorders.

(iii) *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.

■ 10. In § 522.2260, revise paragraphs (a), (d)(1), and (d)(3) to read as follows:

§ 522.2260 Sulfamethazine.

(a) *Specifications*. Each milliliter (mL) of solution contains 250 milligrams (mg) sulfamethazine sodium.

* * * * *

(d) * * *

(1) *Amount*. Initially administer 20 mL for each 50 pounds (lb) of body

weight (100 mg/lb) by intravenous injection, followed by 20 mL per 100 lb of body weight (50 mg/lb) by intravenous injection, daily thereafter. Treatment should not exceed a total of 5 consecutive days.

* * * * *

(3) *Limitations*. Withdraw medication from cattle 10 days prior to slaughter. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 18, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-21721 Filed 8-24-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0755]

RIN 1625-AA00

Safety Zone; ISAF Nations Cup Grand Final Fireworks Display, Sheboygan, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Lake Michigan in Sheboygan, Wisconsin. This zone is intended to restrict vessels from a portion of Sheboygan Harbor during a fireworks display on September 13, 2011. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with this fireworks display.

DATES: This rule is effective from 7:45 until 8:45 p.m. on September 13, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0755 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0755 in the Docket ID box, pressing Enter, 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