

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(C) *Limitations.* Do not slaughter within 44 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating 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.

(ii) 300 mg/mL florfenicol in n-methyl-2-pyrrolidone (inactive vehicle).

(A)(1) *Amount.* 20 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later. Alternatively, 40 mg/kg of body weight as a single subcutaneous injection may be used.

(2) *Indications for use.* For treatment of BRD associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(B)(1) *Amount.* 40 mg/kg of body weight as a single subcutaneous injection.

(2) *Indications for use.* For control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(C) *Limitations.* Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating 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.

(2) [Reserved]

Dated: April 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-8346 Filed 4-17-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Insulin

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 Intervet, Inc. The supplemental NADA provides for the veterinary prescription use of an injectable suspension of porcine insulin zinc for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

DATES: This rule is effective April 18, 2008.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 141-236 providing for the veterinary prescription use of VETSULIN (porcine insulin zinc) Suspension for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus. The application also provides for a lower initial dosage of insulin for dogs. The supplemental NADA is approved as of March 24, 2008, and the regulations are amended in 21 CFR 522.1160 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(d)(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.

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 approval qualifies for 3 years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the indication for use in cats for which this supplement is approved.

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.

■ 2. In § 522.1160, revise paragraphs (a) and (c) to read as follows:

§ 522.1160 Insulin.

(a) *Specifications.* Each milliliter of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

* * * * *

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

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

(2) *Cats—(i) Amount.* Administer an initial dose of 1 to 2 IU by subcutaneous

injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

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

Dated: April 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-8347 Filed 4-17-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG-2008-0267]

Drawbridge Operation Regulation; Illinois Waterway, Joliet, IL 8K Run

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the operations of the Cass Street Drawbridge, across the Illinois Waterway, Mile 288.1, at Joliet, Illinois. The deviation is necessary for the bridge to remain closed to navigation during the effective period for the Joliet City Center Partnership 8K Run.

DATES: This temporary deviation is effective from 8:30 a.m. to 11:30 a.m., May 10, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2008-0267 and are available online at <http://www.regulations.gov>. They are also available for inspection or copying at two locations: 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, and the Robert A. Young Federal Building, Room

2.107F, 1222 Spruce Street, St. Louis, MO 63103-2832, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator, (314) 269-2378.

SUPPLEMENTARY INFORMATION: The Illinois Department of Transportation requested a temporary deviation for the Cass Street Drawbridge, mile 288.1, at Joliet, Illinois across the Illinois Waterway as the drawbridge is along the route of the Joliet City Center Partnership 8K Run. The Cass Street Drawbridge currently operates in accordance with 33 CFR 117.393(c), which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart, except that they need not open from 7:30 a.m. to 8:30 a.m. and from 4:15 p.m. to 5:15 p.m., Monday through Saturday. In order to facilitate the annual event, the drawbridge must be kept in the closed-to-navigation position. This deviation allows the drawbridge to remain closed to navigation from 8:30 a.m. to 11:30 a.m., May 10, 2008.

There are no alternate routes for vessels transiting this section of the Illinois Waterway.

The Cass Street Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 16.5 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

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: April 8, 2008.

Roger K. Wiebusch,

Bridge Administrator.

[FR Doc. E8-8472 Filed 4-17-08; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0139; FRL-8359-9]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of the insecticide thiamethoxam and its metabolite, CGA-322704, in or on soybean, hulls and soybean, aspirated grain fractions. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 18, 2008. Objections and requests for hearings must be received on or before June 17, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0139. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8735; e-mail address: chao.julie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or