

(Lat. 37°17'03" N., long. 100°21'31" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Meade Municipal Airport and within 2.5 miles each side of the 009° bearing from the Meade NDB extending from the 6.5-mile radius to 7 miles north of the airport.

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Issued in Kansas City, MO, on September 23, 1998.

Donovan D. Schardt,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 98-27249 Filed 10-8-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Ivermectin

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 Merial Ltd. The supplemental NADA provides for use of ivermectin Type A medicated articles to make Type B and C medicated swine feeds, to make Type C feed for treatment and control of threadworms (*Strongyloides ransomi*), and as top-dressing for individual treatment of adult swine.

EFFECTIVE DATE: October 9, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, is sponsor of NADA 140-974 that provides for use of Ivomec (ivermectin 0.6%) Type A articles to make ivermectin Type B and C swine feeds. The Type C feeds contain 1.8 grams ivermectin per ton for feeding to weaned, growing and finishing swine, and adult and breeding swine. It is used for treatment and control of gastrointestinal roundworm, kidney worm, and lungworm infections, and lice and mite infestations. The supplemental NADA provides for use of the Type C feeds for treatment and control of threadworms (*Strongyloides ransomi*) infections, specifically treatment and control of "threadworms

(*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation)," and for use as top-dressing for individual treatment of adult swine. The supplemental NADA is approved as of August 10, 1998, and the regulations are amended in § 558.300 (21 CFR 558.300) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.300 is amended by redesignating paragraph (c) as paragraph (d), adding new paragraph (c), and in newly redesignated paragraph (d) inserting several editorial and technical changes and adding a required limitation statement.

This supplemental NADA is for use of approved ivermectin Type A medicated articles to make Type B and C medicated feeds. Ivermectin is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved medicated feed application is required for making Type B or C medicated feeds as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by the requirement for feed mill licenses. Therefore, use of ivermectin Type A medicated articles to make Type B and C medicated feeds as provided in this NADA is limited to manufacture in a licensed feed mill.

Also, the regulation concerning tolerances for ivermectin residues in edible tissues is amended to provide for an acceptable daily intake (ADI) for total ivermectin residues. The ADI is the amount of total drug residue that can be safely consumed by humans every day. Previously, FDA had codified safe concentrations for drug residues. The safe concentrations were confusing because few individuals understood the relationship between safe concentrations, a value representing total residues, and tolerances, the part of the drug residue in a given tissue that is detected by a specific analytical method. To eliminate this confusion, FDA is codifying the ADI.

In addition, the regulations for tolerances for ivermectin residues is further amended to establish a tolerance for ivermectin residues in swine muscle.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 10, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use in swine for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation).

FDA has determined under 21 CFR 25.33(a)(1) and (a)(7) 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.

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 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. Section 556.344 is revised to read as follows:

§ 556.344 Ivermectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

(b) *Tolerances—*(1) *Liver.* A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in liver (target tissue) as follows:

(i) *Cattle.* 100 parts per billion.

- (ii) *Swine*. 20 parts per billion.
- (iii) *Sheep*. 30 parts per billion.
- (iv) *Reindeer*. 15 parts per billion.
- (v) *American bison*. 15 parts per billion.

(2) *Muscle*. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in muscle as follows:

- (i) *Swine*. 20 parts per billion.
- (ii) [Reserved]

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. Section 558.300 is amended by redesignating paragraph (c) as paragraph (d), by adding new paragraph (c) and reserving it, by adding introductory text to newly redesignated paragraph (d), and by revising newly redesignated paragraph (d)(1), to read as follows:

§ 558.300 Ivermectin.

* * * * *

(c) [Reserved]

(d) *Conditions of use*. It is used in swine feed as follows:

(1) *Amount per ton*. For weaned, growing-finishing swine, feed 1.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, feed 1.8 to 11.8 grams of ivermectin (to provide 0.1 milligram per kilogram of body weight per day). For adult and breeding swine, may be top-dressed on daily ration for individual treatment at levels of 18.2 to 1180 grams (to provide 0.1 milligram per kilogram of body weight per day).

(i) *Indications for use*. For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum spp.*, adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus spp.*, adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).

(ii) *Limitations*. For use in swine feed only. Feed as sole ration for 7 consecutive days. Withdraw 5 days before slaughter. Consult your veterinarian for assistance in the

diagnosis, treatment, and control of parasitism.

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Dated: September 28, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-27080 Filed 10-8-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05-98-081]

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, NC

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District has issued a temporary deviation from the regulations governing the operation of the Onslow Beach Swing Bridge across the Atlantic Intracoastal Waterway (AICW), mile 240.7, at Camp Lejeune, North Carolina. Beginning at 7 a.m. on October 15, through 11:59 p.m. on October 16, 1998, the bridge will be maintained in the closed position. This closure is necessary to facilitate extensive repairs and maintain the bridge's operational integrity.

DATES: This deviation is effective from 7 a.m. on October 15, 1998 until 11:59 p.m. on October 16, 1998.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at (757) 398-6222.

SUPPLEMENTARY INFORMATION: The Onslow Beach Swing Bridge and adjoining property are part of the Marine Corps Base (USMC) at Camp Lejeune military reservation, located adjacent to Jacksonville, North Carolina. On September 15, 1998, a letter was forwarded to the Coast Guard by the USMC requesting a temporary deviation from the normal operation of the bridge. The current regulations in Title 33 Code of Federal Regulations, Section 117.821(a)(3), require the Onslow Beach Swing Bridge to open on signal at all times for commercial vessels and on signal for pleasure vessels, except between 7 a.m. and 7 p.m., the draw need only open on the hour and half hour.

The bridge repairs will replace the bridge balance rail, immobilizing the operation of the swing bridge entirely, including the backup system which uses

hydraulic components typically used when the electrical systems are non-operational. Additionally, tugboats, cranes, and barges positioned at the site may impede vessel traffic that could pass under the bridge.

The Coast Guard has informed the known commercial users of the AICW of the bridge closure so that these users can arrange their transits to avoid being negatively impacted by the temporary deviation.

From 7 a.m. on October 15, until 11:59 p.m. on October 16, 1998, this deviation allows the Onslow Beach Swing Bridge across the AICW to remain closed.

Dated: September 29, 1998.

Roger T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[Docket No. CGD05-98-083]

RIN 2115-AE47

Drawbridge Operation Regulations; New Jersey Intracoastal Waterway; Grassy Sound Channel

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations that govern the operation of the Route 47 (George A. Reading) bridge across Grassy Sound Channel, at Intracoastal Waterway (CW) mile 108.9 in Wildwood, New Jersey by requiring two-hours advance notice for bridge openings 24 hours a day beginning at 7 a.m. on October 19, 1998, through 5 p.m. on May 14, 1999. The bridge will be unattended during these time periods and requests for opening will require calling (609) 352-5362. This action is intended to allow the contractor to facilitate sandblasting and painting operations.

DATES: This regulation is effective from 7 a.m. on October 19, 1998 to 5 p.m. on May 14, 1999.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the office of the Commander (Aowb), Fifth District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except