

That airspace extending upward from 700 feet above the surface within an 8.3-mile radius of Cram Field.

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Issued in Kansas City, MO, on September 16, 2004.

Paul J. Sheridan,

Manager, Air Traffic Division, Central Region.

[FR Doc. 04-21530 Filed 9-23-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Ivermectin Liquid

**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 revised labeling, including the addition of four new species of internal parasites, for ivermectin oral liquid used in horses.

**DATES:** This rule is effective September 24, 2004.

**FOR FURTHER INFORMATION CONTACT:** Martine Hartogensis, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7815, e-mail: [martine.hartogensis@fda.gov](mailto:martine.hartogensis@fda.gov).

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 140-439 for EQVALAN (ivermectin) Oral Liquid for Horses. The supplemental application provides for revisions to the labeled indications. Specifically, the supplement provides for the use of ivermectin oral liquid for the treatment and control of *Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocylus* spp., including *Coronocylus coronatus* and *Coronocylus labratus*. The label descriptions of some currently approved parasite genera are also being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature. In addition, under the sub-heading "Small Strongyles," the labeling has been revised to separate the

listing of adult species from the fourth-stage larvae. The supplemental NADA is approved as of August 9, 2004, and 21 CFR 520.1195 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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, Room 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 (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 9, 2004. This marketing exclusivity only applies to the parasites for which new data were required.

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.

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 520

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 520 is 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. Section 520.1195 is amended by revising paragraphs (b), (e)(1)(ii), and (e)(1)(iii) to read as follows:

#### § 520.1195 Ivermectin liquid.

\* \* \* \* \*

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1)(i),

(e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) Nos. 051259, 058829, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

(3) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(ii) *Indications for use.* For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults), *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(B) Large Strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. edentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); Small Strongyles including those resistant to some benzimidazole class compounds (*Cyathostomum* spp. (adult and fourth-stage larvae), *Cylicocylus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); Ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); Hairworms (*Trichostrongylus*

*axeí*(adult)); Large mouth Stomach Worms (*Habronema muscae* (adult)); Stomach Bots (*Gastrophilus* spp. (oral and gastric stages)); Lungworms (*Dictyocaulus arnfieldi* (adult and fourth-stage larvae)); intestinal threadworms (*Strongyloides westeri* (adult)); Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(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.

\* \* \* \* \*

Dated: September 14, 2004.

**Daniel G. McChesney,**

*Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.*

[FR Doc. 04-21415 Filed 9-23-04; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[CGD05-04-175]

RIN 1625-AA08

#### Special Local Regulations for Marine Events; Virginia Beach, VA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of implementation of regulation.

**SUMMARY:** The Coast Guard is implementing the special local regulations at 33 CFR 100.522 during the Neptune Festival Fireworks to be held September 25, 2004, in the vicinity of the Virginia Beach Fishing Pier, Virginia Beach, VA. This action is necessary to provide for the safety of life on navigable waters during the event. The effect will be to restrict general navigation in the regulated area for the safety of participants and vessels transiting the event area.

**DATES:** 33 CFR 100.522 will be enforced from 8:45 p.m. to 10 p.m. on September 25, 2004.

**FOR FURTHER INFORMATION CONTACT:** Michael Bowling, Project Manager, Coast Guard Group Hampton Roads, VA, at (757) 483-8567.

**SUPPLEMENTARY INFORMATION:** The Virginia Beach Neptune Festival will sponsor the fireworks display on September 25, 2004 over the coastal waters in the vicinity of the Virginia

Beach Fishing Pier, Virginia Beach, Virginia. The pyrotechnic display will be launched from the fishing pier located within the regulated area. A fleet of spectator vessels is expected to gather nearby to view the event. Therefore, to ensure the safety of spectators and transiting vessels, 33 CFR 100.522 will be enforced for the duration of the event. Under provisions of 33 CFR 100.522, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel.

In addition to this notice, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Dated: September 14, 2004.

**Ben R. Thomason, III,**

*Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.*

[FR Doc. 04-21524 Filed 9-23-04; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[CGD05-04-166]

RIN 1625-AA-09

#### Drawbridge Operation Regulations; Delaware River, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Delair Railroad Bridge across the Delaware River mile 104.5, between Philadelphia, PA, and Delair, NJ. This deviation allows the drawbridge to remain in the closed-to-navigation position from 8 a.m. to 4 p.m., on nine consecutive Mondays on September 27 through November 22, 2004, to facilitate replacement of bridge timbers.

**DATES:** This deviation is effective from 8 a.m. on September 27, 2004, to 4 p.m. on November 22, 2004.

**FOR FURTHER INFORMATION CONTACT:** Bill Brazier, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398-6422.

**SUPPLEMENTARY INFORMATION:** New Jersey Transit, who operates their trains and controls the signaling system at the Delair Railroad Bridge, has requested a temporary deviation from the operating regulation to facilitate needed replacement of bridge timbers.

To facilitate this replacement, the vertical lift-span will be locked in the closed-to-navigation position from 8 a.m. to 4 p.m. on nine consecutive Mondays: on September 27; on October 4, 11, 18, and 25; and on November 1, 8, 15, and 22, 2004. During these stages, the work requires completely immobilizing the operation of the vertical-lift span in the closed-to-navigation position. At all other times, the bridge will operate in accordance with the current operating regulations outlined in 33 CFR 117.716.

The Coast Guard has informed the known users of the waterway of the closure periods for the bridge so that these vessels can arrange their transits to minimize any impact caused by the temporary deviation.

The District Commander has granted temporary deviation from the operating requirements listed in 33 CFR 117.35 for the purpose of repair completion of the drawbridge. The temporary deviation allows the Delair Railroad Bridge across the Delaware River mile 104.5, between Philadelphia, PA and Delair, NJ, to remain closed to navigation from 8 a.m. to 4 p.m. on nine consecutive Mondays: on September 27; on October 4, 11, 18, and 25; and on November 1, 8, 15, and 22, 2004.

Dated: September 20, 2004.

**Waverly W. Gregory, Jr.,**

*Chief, Bridge Administration Branch, Fifth Coast Guard District.*

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## DEPARTMENT OF THE INTERIOR

### National Park Service

#### 36 CFR Part 7

RIN 1024-AD14

#### Delaware Water Gap National Recreation Area, Pennsylvania and New Jersey; U.S. Route 209 Commercial Vehicle Fees

**AGENCY:** National Park Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the special regulations for Delaware Water Gap National Recreation Area. It changes the fee schedule for those commercial vehicles permitted to travel