

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel Paste

**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 Virbac AH, Inc. The supplemental NADA provides revised labeling for ivermectin and praziquantel oral paste used in horses for the treatment and control of various internal parasites.

**DATES:** This rule is effective November 1, 2005.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: [melanie.berson@fda.gov](mailto:melanie.berson@fda.gov).

**SUPPLEMENTARY INFORMATION:** Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed a supplement to NADA 141-215 for EQUIMAX (ivermectin 1.87%/praziquantel 14.03%) Paste for horses. This supplement amends product labeling to separate parasite life stages in the indications section. The supplemental NADA is approved as of September 16, 2005, and the regulations in 21 CFR 520.1198 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. The current regulations for ivermectin and praziquantel paste are also being revised to remove redundant language. These changes are being made to improve the readability of the regulations.

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.

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 520.1198 is amended by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

#### § 520.1198 Ivermectin and praziquantel paste.

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(i) Tapeworms—*Anoplocephala perfoliata*; 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.

(ii) Tapeworms—*Anoplocephala perfoliata*; Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp., *Cylicocylus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.; 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.; 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.

\* \* \* \* \*

Dated: October 14, 2005.

**Steven D. Vaughn,**

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

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[COTP Jacksonville 05-140]

RIN 1625-AA87

#### Security Zone; Sea Buoy at the Entrance of St. Mary's River to Kings Bay, GA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary moving security zone around foreign naval submarines in transit within the area between 12 nautical miles offshore from the baseline, also known as the shoreline, at the mouth of the St. Mary's River to the Kings Bay Naval Submarine Base, Kings Bay, GA. The security zone includes all waters within 500 yards in

any direction of the submarine. The rule prohibits entry into the security zone without the permission of the Captain of the Port (COTP) Jacksonville or his designated representative. Persons or vessels that receive permission to enter the security zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 100 yards, in any direction, to the submarine. This security zone is needed to ensure public safety and to prevent sabotage or terrorist acts against the submarine.

**DATES:** This rule is effective from 12:01 p.m. on October 20, 2005, until 11:59 p.m. on October 31, 2005.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket [COTP Jacksonville 05–140] and are available for inspection and copying at Coast Guard Sector Jacksonville Prevention Department, 7820 Arlington Expressway, Suite 400, Jacksonville, Florida, 32211, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ensign Kira Peterson at Coast Guard Sector Jacksonville Prevention Department, Florida tel: (904) 232–2640, ext. 108.

#### **SUPPLEMENTARY INFORMATION:**

##### **Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing a NPRM, which would incorporate a comment period before a final rule could be issued, and delay the rule's effective date, is contrary to the public interest because immediate action is necessary to protect the public and waters of the United States.

For the same reasons, 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**. The Coast Guard will issue a broadcast notice to mariners and will place Coast Guard vessels in the vicinity of this zone to advise mariners of the restrictions.

##### **Background and Purpose**

This rule is needed to protect foreign navy submarines from damage or injury from sabotage or other subversive acts, accidents or other causes of a similar nature, or to secure the observance of rights and obligations of the United States. Although this rule is effective

from 12:01 p.m. on October 20, 2005, until 11:59 p.m. on October 31, 2005, the Coast Guard will only enforce this rule when a foreign navy submarine is transiting within the area between 12 nautical miles offshore from the baseline, also known as the shoreline, at the mouth of the St. Mary's River to the Kings Bay Naval Submarine Base, Kings Bay, GA. Anchoring, mooring, or transiting within this zone is prohibited, unless authorized by the Captain of the Port, Jacksonville, Florida or his designated representative. The temporary security zone encompasses all waters within 500 yards around the foreign naval submarine. Vessels or persons authorized to enter the zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 100 yards, in any direction, to the submarine.

##### **Regulatory Evaluation**

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential cost and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under the order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS) because these regulations will only be in effect for a short period of time and the impact on routine navigation is expected to be minimal.

##### **Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominate in their field, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact upon a substantial number of small entities because the regulation will only be enforced for a short period of time within an 11 day window, during vessel transits, and the impact on routine navigation is expected to be minimal. Vessels may still transit safely around the zone and, upon permission of the Captain of the Port or his designated representative, may transit at minimum safe speed through that portion of the

security zone between 200 and 500 yards from the submarine.

##### **Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 204–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

##### **Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

##### **Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

##### **Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Although this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

##### **Taking of Private Property**

This rule will not affect a taking of private property or otherwise have

taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

#### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling

procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### Environment

We have analyzed this rule under Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (34)(g), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165, as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 207–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. A new temporary § 165.T07–140 is added to read as follows:

#### § 165.T07–140 Security Zone; Sea buoy at the entrance of St. Mary's River to Kings Bay, GA.

(a) *Regulated area.* The Coast Guard is establishing a temporary moving security zone around foreign naval submarines when they are within a regulated area 12 nautical miles offshore from the baseline, also known as the shoreline, at the mouth of the St. Mary's River to the Kings Bay Naval Submarine Base, Kings Bay, GA. The temporary security zone encompasses all waters within 500 yards in any direction around a foreign navy submarine transiting within the regulated area.

(b) *Definitions.* The following definitions apply to this section:

*Designated representatives* means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the Captain of the Port (COTP), Jacksonville, Florida, in the enforcement of the regulated navigation areas and security zones.

*Minimum Safe Speed* means the speed at which a vessel proceeds when it is fully off plane, completely settled in the water and not creating excessive wake. Due to the different speeds at which vessels of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to minimum safe speed. In no instance should minimum safe speed be interpreted as a speed less than that required for a particular vessel to maintain steerageway. A vessel is not proceeding at minimum safe speed if it is:

- (1) On a plane;
- (2) In the process of coming up onto or coming off a plane; or
- (3) Creating an excessive wake.

(c) *Regulations.* In accordance with the general regulations in § 165.33 of this part, anchoring, mooring or transiting in the regulated area is prohibited unless authorized by the Coast Guard Captain of the Port Jacksonville, FL or his designated representative. Persons or vessels that receive permission to enter the security zone must proceed at a minimum safe speed, must comply with all orders issued by the COTP or his designated representative, and must not proceed any closer than 200 yards, in any direction, to the submarine.

(d) *Dates.* This section is effective from 12:01 p.m. on October 20, 2005, until 11:59 p.m. on October 31, 2005.

Dated: October 20, 2005.

**David L. Lersch,**

*Captain, U.S. Coast Guard, Captain of the Port Jacksonville.*

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