

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

Display Date 6-27-03  
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Certifier J. Cooke

*DMB*

**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 new animal drug application (NADA) filed by Merial, Ltd. The NADA provides for use of an ivermectin and praziquantel oral paste for the control of various species of internal parasites in horses.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**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: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-214 for ZIMECTERIN GOLD (ivermectin 1.55 percent/praziquantel 7.75 percent) Paste. The application provides for use of an ivermectin and praziquantel oral paste for the control of various species of internal parasites in horses. The NADA is approved as of April 17, 2003, and 21 CFR part 520 is amended by adding new § 520.1198 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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**NADA 141-214**

**NFR**

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 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)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning April 17, 2003.

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 added to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

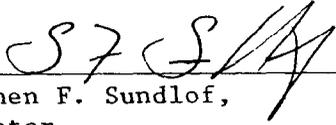
(d) *Conditions of use in horses*—(1) Amount. 200 micrograms ( $\mu\text{g}$ ) per kilogram (/kg) ivermectin (91  $\mu\text{g}$  per pound (/lb)) and 1 mg/kg praziquantel (454  $\mu\text{g}$ /lb) body weight.

(2) *Indications for use*—For treatment and control of 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 including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae)—*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*; *Petrovinema poculatum*; 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*;

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summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dated: 6/20/03  
June 20, 2003.



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