

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed NADA 141-215 for use of EQUIMAX (ivermectin 1.87%/praziquantel 14.03%) Paste in horses for the treatment and control of various species of internal parasites. The NADA is approved as of July 11, 2003, 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.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning July 11, 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 revised to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains:

(1) 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(2) 0.0187 mg (1.87 percent) ivermectin and 0.1403 mg (14.03 percent) praziquantel.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.—(1) No. 050604 for use of product described in paragraph (a)(1) of this section as in paragraphs (d)(1)(i), (d)(2)(i) and (d)(3) of this section.

(2) No. 051311 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1)(ii), (d)(2)(ii), and (d)(3) of this section.

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

(d) *Conditions of use in horses*—(1) *Amount*—(i) 200 micrograms (mcg) per kilogram (/kg) ivermectin (91 mcg per pound (/lb)) and 1 mg/kg praziquantel (454 mcg/lb) body weight.

(ii) 200 mcg/kg ivermectin (91 mcg/lb) and 1.5 mg/kg praziquantel (681 mcg/lb) body weight.

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

(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 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*; and *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*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and 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 including those

resistant to some benzimidazole-class compounds (adults and fourth-stage larvae) (*Cyathostomum* spp., *Cylicocylus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.); 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; and dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(3) *Limitations.* For oral use only. Do not use in horses for food purposes.

Dated: September 8, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

31 CFR Part 1

RIN 1506-AA62

Financial Crimes Enforcement Network; Freedom of Information Act, Privacy Act of 1974; Implementation

AGENCY: Department of the Treasury.

ACTION: Final Rule.

SUMMARY: This document amends the Department of the Treasury's regulations on the disclosure of records under the Freedom of Information Act (FOIA) and its regulations concerning the Privacy Act of 1974 (Privacy Act), by creating new appendices to this subpart setting forth the administrative procedures by which the Financial Crimes Enforcement Network ("FinCEN") will process requests for records made under the FOIA, and setting forth the administrative procedures by which FinCEN will implement the Privacy Act.

EFFECTIVE DATE: September 25, 2003.

FOR FURTHER INFORMATION CONTACT: Christine Schuetz, Attorney-Advisor, Office of Chief Counsel, FinCEN, at (703) 905-3590.

SUPPLEMENTARY INFORMATION: Prior to October 26, 2001, the date of enactment of the Uniting and Strengthening America by Providing Appropriate