

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Meal

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 ivermectin meal for the control of various species of internal parasites in horses.

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

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SUPPLEMENTARY INFORMATION: Merial, Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-241 for ZIMECTERIN-EZ (ivermectin) 0.6% w/w for Horses. The application provides for use of ivermectin meal for the control of various species of internal parasites in horses. The NADA is approved as of December 16, 2004, and part 520 (21 CFR part 520) is amended by adding new § 520.1194 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 December 16, 2004.

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 520.1194 is added to read as follows:

§ 520.1194 Ivermectin meal.

(a) *Specifications.* Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

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(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*. Administer 136 micrograms (mcg) ivermectin per pound (/lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use*. For treatment and control of 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): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* 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.

(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: December 29, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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