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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 [*insert date of publication in the* **Federal Register**].

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.*

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 *Coronocyclus* spp., including *Coronocyclus coronatus* and *Coronocyclus 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, rm. 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.

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(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): *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.

(B) Large Strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. endentatus* (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), *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (*Oxyuris equi* (adult and fourth-stage larvae)); Ascarids (*Parascaris equorum* (adult and third- and fourth-stage larvae)); Hairworms (*Trichostongylus axei*(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.

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Dated: September 14, 2004

September 14, 2004.

Daniel G. McChesney,
Director,
Office of Surveillance and Compliance, Center for Veterinary Medicine.

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