

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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; technical amendment.

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Certifier R. LEDESMA

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SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of an ivermectin solution in sheep for the treatment and control of various internal parasites.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-327 for PRIVERMECTIN (ivermectin) Drench for Sheep. The application provides for oral use of a 0.08 percent ivermectin solution in sheep for the treatment and control of various internal parasites. First Priority's PRIVERMECTIN Drench for Sheep is approved as a generic copy of Merial Limited's IVOMEK Drench for Sheep, approved under NADA 131-392. ANADA 200-327 is approved as of May 15, 2002, and the regulations are amended in § 520.1195 (21 CFR 520.1195) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 520.1195 is also being amended to correctly describe the concentration of the product and to incorporate 21 CFR 520.1194 in a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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.

The agency has determined under 21 CFR 25.33(a)(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 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.

§ 520.1194 [Removed]

2. Section 520.1194 *Ivermectin drench* is removed.

3. Section 520.1195 is revised to read as follows:

§ 520.1195 Ivermectin liquid.

(a) *Specifications*—(1) Each milliliter (mL) contains 10 milligrams (mg) ivermectin.

(2) Each mL of micellar solution contains 0.8 mg ivermectin.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 050604, 051259, 058829, and 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section.

(2) Nos. 050604 and 058829 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

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

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms (mcg) per kilogram (/kg) of body weight as a single dose by stomach tube or as an oral drench.

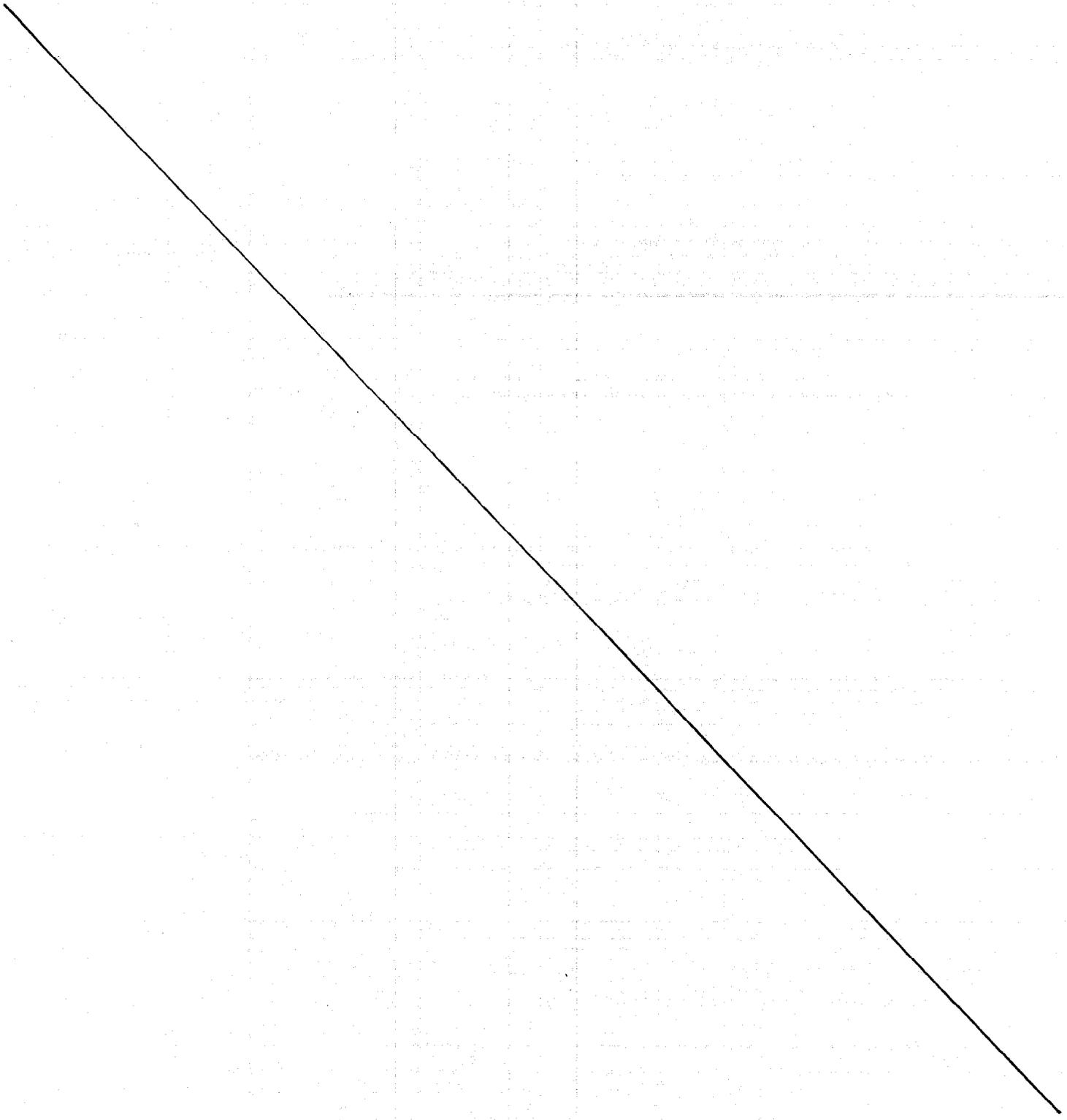
(ii) *Indications for use*. For the treatment and control of large strongyles (*Strongylus equinus* (adult), *S. vulgaris* (adult and arterial larval stages), *S. edentatus* (adult and migrating tissue stages), *Triodontophorus* spp. (adult)); small strongyles, including those resistant to some benzimidazole 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 food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Sheep*—(i) *Amount*. 200 mcg/kg (3 mL/26 pounds) of body weight as a single dose oral drench.

(ii) *Indications for use*. For treatment and control of the adult and fourth-stage larvae of gastrointestinal roundworms (*Haemonchus contortus*, *H. placei* (adults only), *Ostertagia*

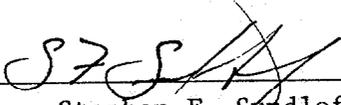
circumcincta, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora* (adults only), *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults only), *Nematodirus battus*, *N. spathiger*, *S. papillosus* (adults only), *Chabertia ovina* (adult only), *Trichuris ovis* (adults only)); lungworms (*D. filaria*); and all larval stages of the nasal bot *Oestrus ovis*.



(iii) *Limitations.* For use in sheep only. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Do not treat sheep within 11 days of slaughter.

Dated: 7/17/02

July 17, 2002.



Stephen F. Sandlof,
Director,
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