

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DMB

Display Date	12-4-01
Publication Date	12-5-01
Certifier	Shore

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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous 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-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-321 for PRIMECTIN™ (ivermectin) Equine Oral Liquid. The application provides for oral use of a 1.0 percent ivermectin solution in horses for the treatment and control of various species of gastrointestinal nematodes, lungworms, stomach bots, and cutaneous larvae and microfilariae. First Priority's PRIMECTIN™ Equine Oral Liquid is approved as a generic copy of Merial Ltd.'s EQVALAN® (ivermectin) Oral Liquid for Horses, approved under NADA 140-439. ANADA 200-321 is approved as of September 7, 2001, 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 5 14.11 (e)(2)(i), 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
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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

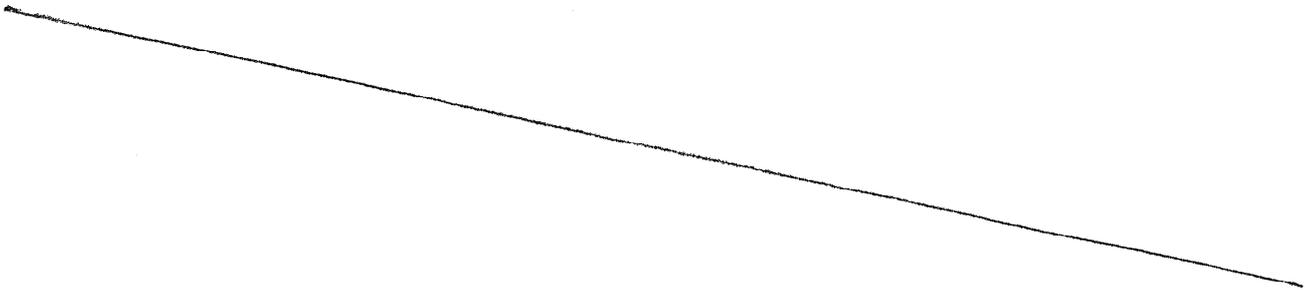
1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1195 is amended in paragraph (b) by adding “058829,” after “051259”; by revising the heading of paragraph (c) and paragraph (c)(1); in paragraph (c)(2) by removing “It is used in horses”; and in paragraph (c)(3) by removing the first sentence to read as follows:

§ 520.1195 Ivermectin liquid.

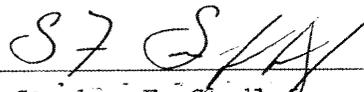
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(c) *Conditions of use in horses*—(1) *Amount*. 200 micrograms per kilogram of body weight as a single dose by stomach tube or as an oral drench.

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Dated: 11/9/01
November 9, 2001.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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