

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin and Clorsulon Injection

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 for an increased period of protection from reinfection with three species of internal parasites following administration of an ivermectin and clorsulon injectable solution to cattle.

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

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: janis.messenheimer@fda.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 140-833 for IVOMEK Plus (ivermectin and clorsulon) Injection for cattle. The application extends the period of persistent effectiveness for *Oesophagostomum radiatum* to 28 days after treatment, and for *Cooperia punctata* and *Trichostrongylus axei* to 21 days after treatment. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the

application. The supplemental NADA is approved as of April 21, 2004, and 21 CFR 522.1193 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 approval qualifies for 3 years of marketing exclusivity beginning April 21, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for the three species of parasites listed previously in this document.

FDA 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 the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.1193 is amended by revising paragraphs (d)(2) and (d)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

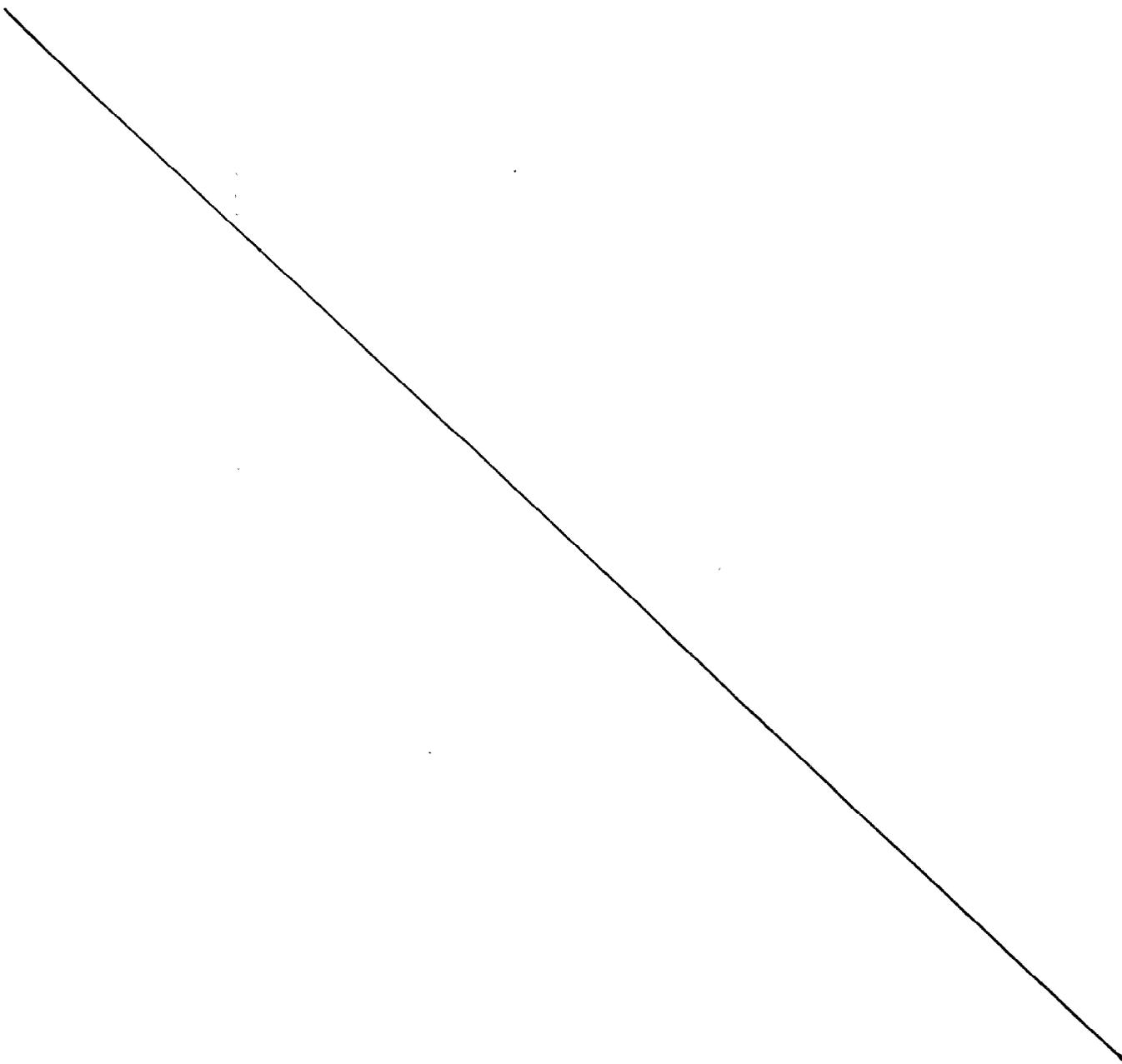
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(d) * * *

(2) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata*

for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of



parasitism. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: May 19, 2004
May 19, 2004.

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