DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Ivermectin 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 of cattle following administration of ivermectin solution by subcutaneous injection.

DATES: This rule is effective September 2, 2004.

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 128–409 for IVOMEC (ivermectin) Injection for Cattle and Swine. The supplemental application provides for an increased period of protection from reinfection with three species of internal parasites of cattle following administration of ivermectin solution by subcutaneous injection. Specifically, the period of persistent effectiveness is increased from 14 days to 28 days for *Oesophagostomum radiatum*, and from 14 days to 21 days for *Trichostrongylus axei* and *Cooperia punctata*. 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 August 16, 2004, and 21 CFR 522.1192 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 August 16, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for *O. radiatum* from 14 days after treatment to 28 days after treatment, and for *T. axei* and *C. punctata* from 14 days after treatment to 21 days after treatment, for which new data were required.

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 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 AND 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 522.1192 is amended in paragraphs (a)(1), (a)(2), and (a)(3) by removing ''sterile aqueous''; and by revising paragraphs (b) and (d)(2)(i) through (d)(2)(iii) to read as follows:

§ 522.1192 Ivermectin injection.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use as in paragraph (d) of this section.

(2) No. 059130 for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section of this section.

* * * * *

(d) * * *

(2) * * *

(i) *Amount.* 200 micrograms per kilogram of body weight by subcutaneous injection.

(ii) *Indications for use*—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*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (scabies) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For No. 059130 in § 510.600(c) of this chapter: It is also used to control infections of *D. viviparus* for 28 days after treatment; *O. ostertagi* for 21 days after treatment; and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment. For No. 050604 in § 510.600(c) of this chapter: To control infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations.* Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Not for intravenous or intramuscular use. 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.

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Dated: August 25, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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