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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 Merck Research Laboratories, Division of Merck & Co., Inc. The supplement provides for subcutaneous use of ivermectin injection as an antiparasitic in ranch-raised foxes.

EFFECTIVE DATE: August 30, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is sponsor of NADA 128–409 which provides for the use of Ivomec® Injection (ivermectin) as an antiparasitic for horses, cattle, reindeer, and swine. The supplement provides for use of 0.27 percent ivermectin as an antiparasitic for treatment and control of ear mites (*Otodectes cynotis*) in ranch-raised foxes. Approval is based in part on data and information in Public Master File (PMF) 5307 established under the National Research Support Project No. 7 (NRSP–7) (formerly the Interregional Research Project No. 4 (IR–4)), Northcentral Region, Michigan State University, East Lansing, MI 48824. The supplemental NADA is approved as of July 13, 1995, and the regulations are amended in § 522.1192 (21 CFR 522.1192) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Also, the heading of § 522.1192 is amended to read ''Ivermectin injection.''

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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 supplement does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1192 is amended by revising the section heading, the heading for paragraph (a)(3), and by adding new paragraph (d)(5) to read as follows:

§ 522.1192 Ivermectin injection.

(a) * * *

(3) *Piglets 70 pounds or less and ranch-raised foxes.* * * *

* * * * *

(d) * * *

(5) *Ranch-raised foxes.* (i) *Amount.* 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

(iii) *Limitations.* For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: August 14, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–21454 Filed 8–29–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

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 Macleod Pharmaceuticals, Inc. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: August 30, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.