Dated: April 16, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12320 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline 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 abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplemental ANADA provides for establishment of a 28-day withdrawal period for subcutaneous use of oxytetracycline injection in cattle and for intramuscular use in swine.

EFFECTIVE DATE: May 17, 1999.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506, filed supplemental ANADA 200–008 that provides for establishment of a 28-day withdrawal period for subcutaneous use in cattle and intramuscular use in swine of Oxytet™ 200 and Bio-Mycin® 200 (oxytetracycline injection). The 28-day withdrawal period for the intravenous and intramuscular use of oxytetracycline injection in cattle, assigned as part of the original approval, remains unchanged. The drug is for intramuscular, subcutaneous, or intravenous treatment of beef cattle and nonlactating dairy cattle as follows: (1) Bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; (2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; (3) foot rot and diptheria caused by *Fusobacterium necrophorum*; (4) bacterial enteritis (scours) caused by *Escherichia coli*; (5) wooden tongue caused by *Actinobacillus lignieresii*; (6) leptospirosis caused by *Leptospira pomona*; and (7) wound infections and acute metritis caused by strains of streptococcal and staphylococcal organisms. The drug is for intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *P. multocida*, and leptospirosis caused by *L. pomona*, and in sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*. The ANADA is approved as of March 16, 1999, and the regulations are amended by revising § 522.1660(d)(2)(iii) (21 CFR 522.1660(d)(2)(iii)) to reflect the approval. Because the current regulation failed to reflect the previously established 36-day withdrawal period for subcutaneous use of oxytetracycline injection in cattle, no revision to § 522.1660(d)(1)(iii) is required for this supplemental approval that establishes a 28-day withdrawal period for subcutaneous use of oxytetracycline injection in cattle. 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 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.

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 522.1660 is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine. Discontinue treatment at least 28 days prior to slaughter when provided by 000010, 000069, 011722, 053389, 059130, and 061623.

Dated: May 3, 1999.

Margaret Ann Miller,

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

[FR Doc. 99–12284 Filed 5–14–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

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

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 two supplemental new animal drug applications (NADA's) filed by Merial Ltd. One supplement provides for use of ivermectin injection, and the other provides for the use of ivermectin and clorsulon injection, for 28-day persistent control of lungworms in cattle. In addition, a tolerance for ivermectin residues in cattle muscle is established.

EFFECTIVE DATE: May 17, 1999.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, is sponsor of NADA 128–409 that provides for use of Ivomec® Injection (1 percent ivermectin) and NADA 140–833 that provides for use of Ivomec® Plus Injection (1 percent ivermectin and 10 percent clorsulon) in cattle. The NADA's provide for use of the drugs for the treatment and control of gastrointestinal roundworm, lungworm,