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]

BILLING CODE 4160–01–F

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,

grub, lice, and mange mite infections, to control infection and to protect from reinfection with *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Haemonchus placei, Trichostrongylus axei, Cooperia punctata, C. oncophora,* and *Oesophagostomum radiatum* for 14 days after treatment. Also, NADA 140–833 provides for treatment and control of liver flukes. Merial Ltd. filed supplements to both NADA's that amend their use to provide for control of infection and protection from reinfection of *Dictyocaulus viviparus* for 28 days after treatment. The supplements are approved as of April 1, 1999, and the regulations are amended in 21 CFR 522.1192(d)(2)(ii) and 522.1193(d)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has revised the tolerances for residues of ivermectin to establish an acceptable daily intake and a swine muscle tolerance (63 FR 54352, October 9, 1998). At this time, FDA further amends the ivermectin residue tolerances in 21 CFR 556.344 to establish a cattle muscle tolerance.

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 these applications 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning April 1, 1999, because the supplements contain substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplements and conducted or sponsored by the applicant. Exclusivity applies only to the additional indication for persistent effectiveness.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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.

§ 522.1192 [Amended]

2. Section 522.1192 *Ivermectin injection* is amended in paragraph (d)(2)(ii) in the last sentence by removing ''*D. viparus* and'' and adding in its place ''*D. viviparus* for 28 days after treatment,''.

3. Section 522.1193 is amended in paragraph (d)(2) by revising the last sentence to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) * * * It is also used to control infections of *D. viviparus* for 28 days afer 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.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

5. Section 556.344 is amended by adding paragraph (b)(2)(ii) to read as follows:

§ 556.344 Ivermectin.

* * * * *

(b) * * *

(2) * * *

(ii) *Cattle.* 10 parts per billion.

Dated: May 3, 1999.

Margaret Ann Miller,

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

[FR Doc. 99–12286 Filed 5–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Sulfadimethoxine with Ormetoprim

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 Roche Vitamins, Inc. The supplemental NADA provides for use of sulfadimethoxine/ormetoprim type A medicated articles to make type C medicated chukar partridge feeds used for the prevention of coccidiosis. Also, FDA is amending the regulations to reflect tolerances for residues of sulfadimethoxine and for ormetoprim in edible chukar partridge tissues.

EFFECTIVE DATE: May 17, 1999.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 40–209 that provides for use of Rofenaid® 40 (113.5 grams per pound (g/lb) (25 percent) sulfadimethoxine with 68.1 g/lb (15 percent) ormetoprim) type A medicated articles to make type C chukar partridge feeds containing 113.5 grams per ton (g/t) sulfadimethoxine and 68.1 g/t ormetoprim. The type C chukar partridge feeds are fed continuously to young birds up to 8 weeks of age for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*. The supplemental NADA is approved as of April 1, 1999. The regulations are amended in 21 CFR 558.575 to redesignate paragraph (c) as paragraph (d), to reserve paragraph (c), to amend paragraph (a) to reflect the redesignation and to reflect the approval, and to add paragraph (d)(7) to further reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, tolerances are established for sulfadimethoxine and for ormetoprim residues in edible chukar partridge tissues. The regulations are amended in 21 CFR 556.490 and 556.640, accordingly.