SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is sponsor of NADA 140–833, which provides for the use of Ivomec® Plus Injection (1 perecent ivermectin and 10 percent clorsulon) for cattle for the treatment and control of gastrointestinal roundworm, lungworm, grub, lice, and mange mites. The supplement provides for control of infections of *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. The supplement is approved as of February 24, 1997, and the regulations are amended in 21 CFR 522.1193(d)(2) 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 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, 12420 Parklawn Dr., rm. 1–23, 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 supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 24, 1997, because the supplement contains 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 supplement and conducted or sponsored by the applicant. Exclusivity applies only to the additional indications.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1193 is amended by adding a new sentence to the end of paragraph (d)(2) to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) * * * It is also used to control infections of *D. viviparus* and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

* * * * *

Dated: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–7544 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride 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 Boehringer Ingelheim Animal Health, Inc. The supplemental NADA provides for the subcutaneous use (in addition to the approved intravenous and intramuscular use) of 100 milligrams/milliliter (mg/mL) of oxytetracycline hydrochloride injection in cattle for the treatment of diseases caused by oxytetracycline susceptible organisms, for a 2-day withdrawal period following the subcutaneous use, and for a 13-day withdrawal period following the intramuscular and intravenous use.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64502, is the sponsor of NADA 97–452, formerly sponsored by Fermenta Animal Health Co. The firm has filed a supplement to NADA 97–452, which provides for subcutaneous use of 100 mg/mL of oxytetracycline hydrochloride injection in addition to the approved intravenous and intramuscular use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., caused by organisms susceptible to oxytetracycline. In cattle, a 2-day withdrawal period is required following subcutaneous use, and a 13-day withdrawal period is required following intramuscular and intravenous use. The product is also approved for intramuscular and intravenous use in swine. The supplemental NADA is approved as of February 21, 1997, and the regulations are amended in 21 CFR 522.1662a(g)(3)(i)(*c*) to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, 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 approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 21, 1997, because the supplemental application contains substantial evidence of the 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 supplement and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1662a is amended by revising paragraph (g)(3)(i)(*c*) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(g) * * *

(3) * * *

(i) * * *

(*c*) *Limitations.* Administer by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 milligrams of oxytetracycline per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 48 hours, consult a veterinarian. Do not inject more than 10 milliliters per injection site intramuscularly in adult cattle; no more than 1 milliliter per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

Dated: March 14, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7542 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Chlortetracycline; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations that provided for approval of five supplemental new animal drug applications (NADA's) filed by Hoffmann-LaRoche, Inc.; Pfizer, Inc.; ALPHARMA, Inc.; ADM Animal Health & Nutrition Div.; and PennField Oil Co. to reflect conclusions of the National Academy of Sciences/National Research Council (NAS/NRC) review of the use of chlortetracycline Type A articles to make certain Type C medicated feeds, and FDA's conclusions based on that review.

DATES: Effective March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 9, 1996 (61 FR 35949), FDA published a document reflecting approval of the NAS/NRC supplements for Hoffmann–LaRoche's NADA 48–761, Pfizer's NADA's 92–286 and 92–287, ALPHARMA's NADA 46–699, ADM Animal Health and Nutrition Div.'s NADA 48–480, and PennField Oil's NADA 138–935. The July 9, 1996, document failed to include certain amendments to the regulation including a warning against use of certain medicated articles in duck eggs for human food.

In addition, 21 CFR 558.128(c) is redesignated as paragraph (d) and new paragraph (c) is reserved for future use to provide for more uniformity, flexibility, and consistency in the regulations.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.128 [Amended]

2. Section 558.128 *Chlortetracycline* is amended by redesignating paragraph (c) as paragraph (d), by reserving new paragraph (c), and by amending newly redesignated paragraph (d) as follows:

a. In paragraph (d)(1)(vi), in the ''Limitations'' column in the second entry by adding a second sentence to read ''Do not feed to ducks producing eggs for human consumption.''

b. In paragraph (d)(1)(xii), in the ''Limitations'' column in the first entry by removing the word ''excluding'' in the second phrase and adding in its place the word ''including'', and in the first and third entries by adding a new first sentence to read ''Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day.''

c. In paragraph (d)(1)(xvii), in the third column, in entry 1. by removing the phrase ''Cattle (under 700 lb)'' and adding in its place ''Beef cattle''.

Dated: March 13, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7547 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

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 Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of a 90.7 grams per pound (g/lb) (200 g/kilogram (kg)) monensin Type A medicated article for making Type B and C medicated cattle and goat feeds.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1674.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735, which provides for using a 90.7 g/lb (200 g/kg) monensin Type A medicated article to make monensin Type B and C medicated cattle and goat feeds.

The supplemental NADA is approved as of February 6, 1997, and the regulations are amended in 21 CFR