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

558.355(b)(7) and (b)(14) to reflect the approval.

The supplemental approval is for a higher concentration of Type A article to make currently approved Type B and C feeds, and it does not affect the basis of approval of, or conditions of use in, the currently approved application. Therefore, no additional safety or effectiveness data were required for this approval, and a freedom of information summary is not required. A summary of the data and information submitted to support the previously approved 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 does not qualify for marketing exclusivity because the supplement does not contain substantial evidence of effectiveness of the drug involved, any studies of animal safety, or 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)(iii) 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 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).

### § 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (b)(7) by removing the phrase ''and 80'' and adding in its place ''80, and 90.7'' and in paragraph (b)(14) by removing the phrase ''and 80'' and adding in its place '', 80, and 90.7''.

Dated: March 13, 1997.

**Robert C. Livingston,**

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

[FR Doc. 97–7546 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

## 21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Melengestrol Acetate

**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 Pharmacia & Upjohn Co. The supplemental NADA's provide for the use of dry and liquid melengestrol acetate (MGA) Type A medicated articles to manufacture certain Type B and Type C medicated feeds for heifers intended for breeding for suppression of estrus (heat).

**EFFECTIVE DATE:** March 26, 1997.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA's 34–254 and 39–402 providing for use of dry and liquid MGA Type A medicated articles to manufacture certain Type B and Type C medicated feeds for heifers intended for breeding for suppression of estrus (heat). The supplements are approved as of February 18, 1997, and the regulations are amended in § 558.342 (21 CFR 558.342) by adding new paragraph (d)(7) to reflect the approvals.

In addition, certain mixing directions for liquid feeds are required for use of MGA liquid Type A articles to manufacture Type B medicated feeds. Those directions had not been codified previously in the MGA regulations. At this time, the regulations are amended to include those directions in new § 558.342(c) *Special considerations* and existing paragraph (c) is redesignated as paragraph (d).

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)), these approvals qualify for 3 years of marketing exclusivity beginning February 18, 1997, because the supplements contain substantial evidence of effectiveness of the drugs involved, 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 only applies to use in heifers intended for breeding for suppression of estrus.

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 558**

Animal drugs, Animal feeds.

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 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).

2. Section 558.342 is amended by redesignating paragraph (c) as paragraph (d) and by adding new paragraphs (c) and (d)(7) to read as follows:

### § 558.342 Melengestrol acetate.

* * * * *

(c) *Special considerations.* (1) Type B medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid Type B feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than