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

10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid Type B feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A positionally stable melengestrol acetate liquid Type B feed will not be subject to the requirements for mixing directions prescribed in paragraphs (c)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(d) * * *

(7) *Amount.* 0.5 milligram per head per day.

(i) *Indications for use.* For suppression of estrus (heat).

(ii) *Limitation.* Heifers intended for breeding. Do not exceed 24 days of feeding. Administer 0.5 to 2.0 pounds per head per day of Type C feed containing 0.25 to 1.0 milligram of melengestrol acetate per pound to provide 0.5 milligram of melengestrol acetate per head per day. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.

Dated: March 13, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7545 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Salinomycin

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 Hoffmann-LaRoche, Inc. The supplement provides for use of an approved salinomycin Type A medicated article to make Type C roaster and replacement chicken feeds used for prevention of certain forms of coccidiosis.

EFFECTIVE DATE: May 27, 1997.

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: Hoffmann-LaRoche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199, filed supplemental NADA 128–686 that provides for use of a 30-gram-per-pound salinomycin Type A article (as salinomycin sodium) to make Type C roaster and replacement (breeder and layer) chicken feeds containing 40 to 60 grams per ton salinomycin sodium activity for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.* This supplement is approved as of February 3, 1997, and the regulations are amended in 21 CFR 558.550 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 (the 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 3, 1997, because the supplement 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 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.

This approval is for use of salinomycin Type A medicated articles to make Type C medicated feeds. Salinomycin is a category I drug as defined in 21 CFR 558.3(b)(1)(i). As provided in 21 CFR 558.4(b), an approved Form FDA 1900 is not required for making a Type C medicated feed as provided in the NADA. Under section 512(m) of the act, as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by feed mill licensing.

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

2. Section 558.550 is amended by redesignating paragraph (b)(3) as paragraph (b)(4) and by adding new paragraph (b) (3) to read as follows

§ 558.550 Salinomycin.

* * * * *

(b) * * *

(3) *Roaster and replacement (breeder and layer) chickens*: It is used as follows:

(i) *Amount per ton.* Salinomycin 40 to 60 grams.

(ii) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(iii) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to horses or adult turkeys.

Dated: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–7543 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