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

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 monensin Type A medicated articles to make a revised formulation of a free-choice Type C medicated feed for pastured cattle for increased rate of weight gain.

EFFECTIVE DATE: March 26, 1997.

ADDRESSES: Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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, is the sponsor of NADA 95–735, which provides for use of a monensin Type A medicated article to make a monensin Type C medicated feed/free-choice mineral granule containing 1,620 grams monensin per ton to be fed at 50 to 200 milligrams per head per day free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain.

Elanco Animal Health, Division of Eli Lilly and Co. filed a supplemental NADA that provides for a revised formulation of the Type C medicated feed/free-choice granule to properly reflect the salt and mineral content of the product. The supplemental NADA is approved as of March 26, 1997, and the regulations are amended in 21 CFR 558.355(f)(3)(x)(*b*) to reflect the approval.

In addition, § 558.355(f)(3)(x)(*b*) is amended in the table to correct some editorial and typographical errors in the entry for ''Ground limestone (33% calcium)'' and in the entries for ''6–01–080'' and ''4–04–152,'' respectively.

Approval of this supplement does not require a freedom of information summary because the approval concerns a change in salt and mineral content of the product. This change does not affect the product's safety or effectiveness. Therefore, no additional data was required for this approval. Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA–305) (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 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 the table in paragraph (f)(3)(x)(*b*), in the first column, in the entry for ''Ground limestone (33% calcium)'' by adding the phrase ''or calcium carbonate (38% calcium)'' and in the third column in the first and third entries by removing the numbers ''6–01–080'' and ''4–04–152'' and adding in their place the numbers ''6–01–082'' and ''4–04–695'', respectively.

Dated: March 13, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7551 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Change of Scientific Nomenclature

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of scientific nomenclature from *Corynebacterium* to *Actinomyces (Corynebacterium).* This change of nomenclature is necessary due to the scientific reclassification of the organism.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., 2001 West Main St., P.O. Box 708, Greenfield, IN 46140, has informed FDA that the scientific nomenclature for the bacterial organism *Corynebacterium pyogenes* has been changed to *Actinomyces (Corynebacterium) pyogenes.* This change of nomenclature is necessary due to scientific reclassification of the organism. The organism causes liver abscesses in cattle. Accordingly, the agency is amending the regulations in 21 CFR 558.355(f)(3)(ii)(*a*) and (f)(3)(ix)(*a*) and 558.625(f)(1)(i)(*b*) to reflect this change.

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).

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraphs (f)(3)(ii)(*a*) and (f)(3)(ix)(*a*) by removing the word ''*Corynebacterium*'' and adding in its place the words ''*Actinomyces* (*Corynebacterium*)''.

§ 558.625 [Amended]

3. Section 558.625 *Tylosin* is amended in paragraph (f)(1)(i)(*b*) by removing the word ''*Corynebacterius*'' and adding in its place the words ''*Actinomyces* (*Corynebacterium*)''.

Dated: March 13, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7603 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD–040–FOR]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.