SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, PO Box 4010, Clinton, NJ 08809–4010, filed supplemental NADA 140–897 that provides for Revalor®-IS ear implants containing 80 milligrams (mg) trenbolone acetate (TBA) and 16 mg estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Hoechst Roussel Vet also filed supplemental NADA 140–992 that provides for Revalor®-IH ear implants containing 80 mg TBA and 8 mg estradiol for heifers fed in confinement for slaughter for increased rate of weight gain.

The supplemental NADA's are approved as of June 19, 2000, and the regulations are amended in 21 CFR 522.2477 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

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 approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning June 19, 2000, because the applications contain substantial evidence of the effectiveness of the drugs 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 applications and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the implants approved in these supplemental NADA's.

The agency has determined under 21 CFR 25.33(a)(2) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 522.2477 is amended by revising the first sentence in paragraph (b), by adding paragraph (d)(1)(i)(D), and by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii), (d)(2)(iii), and (d)(3) of this section. * * *

* * * * *

(d) * * *

(1) * * *

(i) * * *

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets), or 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(2) * * *

(i) *Amount.* (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B) of this section.

(B) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use.* (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

* * * * *

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18822 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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. The supplemental NADA provides for use of monensin Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding for the prevention and control of coccidiosis, and increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). A technical correction is also being made.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735 that provides for use of RUMENSIN® 80 (80 grams per pound (g/lb) of monensin as monensin sodium) Type A medicated article to make Type C medicated feed formulated as mineral granules for free-choice feeding to pasture cattle. The free-choice medicated mineral granules contain 1,620 g/ton monensin and are used for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). The supplemental NADA is approved as of July 7, 2000, and the regulations are amended in § 558.355(f)(3)(x) (21 CFR 558.355(f)(3)(x)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.355(d)(6) is revised to reflect current precautionary statements regarding the ingestion of monensin-containing formulations by unapproved species.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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

2. Section 558.355 is amended by revising paragraphs (d)(6), (f)(3)(x)(*a*), and (f)(3)(x)(*c*) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(6) The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

* * * * *

(f) * * *

(3) * * *

(x) * * *

(*a*) *Indications for use.* For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

* * * * *

(*c*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. Do not feed to lactating dairy cattle. The product's effectiveness in cull cows and bulls has not been established. Consumption by unapproved species may result in toxic reactions. A feed manufacturing facility must possess a medicated feed mill license issued under § 515.20 of this chapter in order to manufacture this free-choice Type C feed.

* * * * *

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18821 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Penicillin; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect a previously approved 227 grams per pound (g/lb) strength of penicillin G Type A medicated article for use in the feed of several domestic species which was omitted from the regulation in the 1998 notice of approval.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 046–668 that provides for use of Penicillin 100 (100 g/lb penicillin G procaine) and Penicillin 50 (227 g/lb penicillin G procaine) Type A medicated articles to make Type C medicated feeds used for increased rate of weight gain and improved feed efficiency in poultry and swine. In its approval letter of April 10, 1998, to Pfizer, Inc., the Center for Veterinary Medicine approved the use of these products to make Type C medicated feeds, but did not codify the approval of the 227 g/lb strength of Type A medicated article for this sponsor (63 FR 36179, July 2, 1998). At this time, 21 CFR 558.460(b) is amended by adding the 227 g/lb strength of Type A medicated article to reflect the 1998 approval.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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

§ 558.460 [Amended]

2. Section 558.460 *Penicillin* is amended in the first sentence in paragraph (b) by adding ''and 227'' after ''To 000069, 100''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18872 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Neomycin Sulfate

AGENCY: Food and Drug Administration, HHS.