that the implant is not for use in bull calves intended for reproduction. The basis for approval is discussed in the freedom of information summary.

In addition, due to enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, the paragraph concerning National Academy of Science/National Research Council status is outdated. At this time, 21 CFR 522.1940 is amended by removing paragraph (d)(2)(iv).

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 qualifies for 3 years of marketing exclusivity beginning January 22, 1997, because the application contains substantial evidence of the effectiveness of the drug 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 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.

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).

§ 522.1940 [Amended]

2. Section 522.1940 *Progesterone and estradiol benzoate in combination* is amended in paragraph (d)(1)(iii) by removing the phrases ''For 000033:'' and ''For 021641: Do not use in calves intended for reproduction.'' and by removing paragraph (d)(2)(iv).

Dated: February 10, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4517 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Salicylic Acid; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations concerning the use of salicylic acid to correct a certain typographical error. This action is being taken to clarify and improve the accuracy of the regulations.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: FDA has found an error concerning the amount of salicylic acid per dose. In 21 CFR 529.2090(a)(1) that error has been incorporated into the agency's animal drug regulations. FDA is correcting this error. The approved concentration is 0.55 grain of salicylic acid per dose, not 0.55 gram of salicylic acid.

List of Subjects in 21 CFR Part 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.2090 [Amended]

2. Section 529.2090 *Salicylic acid* is amended in paragraph (a)(1) by removing the word ''gram'' and by adding in its place the word ''grain''.

Dated: January 31, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4516 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol Acetate, Monensin, and Tylosin

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 Pharmacia & Upjohn Co. The supplement provides for the use of separately approved Type A medicated articles containing melengestrol acetate (dry form only), monensin, and tylosin to manufacture certain combination drug, dry, meal Type B medicated feeds for use in making Type C medicated feeds. The feeds are for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus, and reduced incidence of liver abscesses.

EFFECTIVE DATE: February 25, 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, 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 138–792, which provides for combining separately approved melengestrol acetate (MGA) (dry form only), monensin sodium, and tylosin phosphate Type A medicated articles to manufacture dry, meal Type B medicated feeds used to make Type C medicated feeds for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses. The supplement is approved as of December 17, 1996, and 21 CFR 558.342 is amended in paragraph (c)(5)(iii)(C) to reflect the approval.

Approval of this supplement which provides for use of a different physical

form of Type B feed did not require reevaluation of the safety or effectiveness data supporting the NADA or the submission of any new data. Therefore, a freedom of information summary is not required.

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 does not qualify for marketing exclusivity because the supplement does not contain 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)(ii) 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).

§ 558.342 [Amended]

2. Section 558.342 *Melengestrol acetate* is amended in paragraph (c)(5)(ii)(C) by removing the word ''pelleted''.

Dated: January 31, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4514 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Bambermycins

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 Hoechst-Roussel Agri-Vet Co. The supplement provides for using liquid bambermycins Type B medicated feeds to make Type C medicated feeds for cattle fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: February 25, 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: Hoechst-Roussel Agri-Vet Co., Route 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, filed supplemental NADA 141–034 that provides for using 10-gram per pound (g/lb) Flavomycin® (bambermycins) Type A medicated articles to make 40 to 800 g/ton liquid Type B medicated feeds, the liquid Type B feeds used to make dry Type C medicated feeds. The Type C feeds containing 1 to 4 g/ton bambermycins are for cattle fed in confinement for slaughter to provide 10 to 20 milligrams bambermycins per head per day for increased rate of weight gain and improved feed efficiency. The regulations are amended in § 558.95 (21 CFR 558.95) by adding new paragraph (a)(5), by redesignating paragraph (b) as paragraph (d), and by revising newly redesignated paragraph (d)(4)(i)(*b*) to reflect the approval.

Furthermore, use of liquid Type B feeds to make Type C feeds requires publication of specifications and expiration information. New § 558.95(b) is established to reflect the Type B feed specifications and expiration information. In the interest of issuing uniform regulations in the future, new § 558.95(c) is also established at this time and reserved for future use.

Approval of this supplement did not require submission of additional safety or efficacy data. A freedom of information (FOI) summary as in 21 CFR part 20 and 514.11(e)(2)(ii) is not required. An FOI summary submitted to support approval of the original application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, from 9 a.m. to 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 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 558.95 is amended by adding new paragraph (a)(5), by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b), by adding and reserving paragraph (c), and by adding a new fourth sentence to newly redesignated paragraph (d)(4)(i)(*b*), to read as follows:

§ 558.95 Bambermycins.

(a) * * *

(5) 10 grams of activity per pound to 012799 in § 510.600(c) of this chapter to make 40 to 800 gram/ton Type B feeds for use as in paragraph (d)(4)(i) of this section.

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) * * *

(4) * * *

(i) * * *