1996, and the regulations are amended by revising 21 CFR 520.2220a(b) 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.

FDA has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually of 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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.2220a [Amended]

2. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (b) by removing ''000069 and 057561'' and adding in its place ''000069, 054273, and 057561''.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–4515 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Suspension and Tablets

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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplements provide that veterinary prescriptions are no longer required for use of lufenuron tablets for dogs and oral suspension for cats.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish P1., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, filed supplemental NADA 141–026 that provides for oral administration of Program® (lufenuron) suspension for cats and kittens for control of flea populations and supplemental NADA 141–035 that provides for oral administration of Program® (lufenuron) tablets for dogs and puppies for prevention and control of flea populations. The supplemental NADA's provide that veterinary prescriptions are no longer required. The supplemental NADA's are approved as of December 31, 1996, and the regulations are amended by revising 21 CFR 520.1288(c)(3) and 520.1289(c)(3) to remove the limitation for veterinary prescription use.

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.

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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1288 [Amended]

2. Section 520.1288 *Lufenuron tablets* is amended in paragraph (c)(3) by removing the last sentence.

§ 520.1289 [Amended]

3. Section 520.1289 *Lufenuron suspension* is amended in paragraph (c)(3) by removing the last sentence.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–4513 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Progesterone and Estradiol Benzoate

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 Ivy Laboratories, Inc. The supplemental NADA provides for use of a progesterone-estradiol benzoate ear implant in suckling beef heifer calves for increased rate of weight gain.

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, 301–827–0217.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 110–315, which provides for use of a progesterone-estradiol benzoate ear implant in suckling beef heifer calves for increased rate of weight gain. Studies have shown no detrimental effects on reproduction after use of the implants in heifer calves. The supplement is approved as of January 22, 1997, and the regulations are amended in 21 CFR 522.1940(d)(1)(iii) to reflect the approval by limiting the use to indicate

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