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 determined under 21 CFR 25.24(d)(1)(i) 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 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).

§ 520.1044c [Amended]

2. Section 520.1044c *Gentamicin sulfate soluble powder* is amended in paragraph (b) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 057561''.

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–14109 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone 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 an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Inc. The ANADA provides for the use of trenbolone acetate implants for improved feed efficiency in growing-finishing feedlot steers and increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers.

EFFECTIVE DATE: May 29, 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, has filed ANADA 200–224, which provides for the use of trenbolone acetate implants for improved feed efficiency in growing-finishing feedlot steers and increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers.

The ANADA is approved as a generic copy of Roussel UCLAF, NADA 138–612;

Finaplix®–S and Finaplix®–H. ANADA 200–224 is approved as of April 30, 1997, and the regulations are amended in 21 CFR 522.2476 to reflect the approval. The basis for 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.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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).

§ 522.2476 [Amended]

2. Section 522.2476 *Trenbolone acetate* is amended in paragraph (b) by adding the phrase ''and 021641'' after the number ''012579''.

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–14104 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Halothane

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 an abbreviated new animal drug application (ANADA) filed by Halocarbon Laboratories, Division of Halocarbon Products Corp. The ANADA provides for the use of halothane for induction and maintenance of general anesthesia in dogs, cats, and other non-food animals.

EFFECTIVE DATE: May 29, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661, has filed ANADA 200–200, which provides for the use of halothane for induction and maintenance of general anesthesia in dogs, cats, and other non-food animals.

The ANADA is approved as a generic copy of Fort Dodge Laboratories, Inc.'s, NADA 14–170 Halothane. ANADA 200–200 is approved as of April 10, 1997, and the regulations are amended in 21 CFR 529.1115(b) to reflect the approval. The basis for 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.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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).

§ 529.1115 [Amended]

2. Section 529.1115 *Halothane* is amended in paragraph (b) by adding after ''000856'' the phrase ''and 012164''.

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–14102 Filed 5–28–97; 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; Salinomycin, Roxarsone, Bacitracin Methylene Disalicylate

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-La Roche, Inc. The supplemental NADA provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing salinomycin with roxarsone and bacitracin methylene disalicylate.

EFFECTIVE DATE: May 29, 1997

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2604.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110–1199, filed supplemental NADA 135–321 which provides for use of single ingredient Type A medicated articles containing Bio-Cox® (salinomycin as salinomycin sodium) 30 grams-per-pound (g/lb), BMD® (bacitracin methylene disalicylate) 30, 50, 60, or 75 g/lb bacitracin activity, 3-Nitro® (roxarsone) 45.4, 90, or 227 g/lb roxarsone activity, to make Type C broiler chicken feeds containing 40 to 60 g per ton (g/t) salinomycin sodium, 34.1 or 45.4 g/t roxarsone, and 4 to 50 g/t bacitracin methylene disalicylate, for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for increased rate of weight gain. Use of 34.1 or 45.4 g/t roxarsone is indicated to meet the *E. tenella* challenge, which varies with environmental and management conditions. The supplement is approved as of May 29, 1997. The basis of approval is discussed in the freedom of information summary.

Also, 21 CFR 558.550 is amended to redesignate existing paragraph (b) as paragraph (d) and to add new paragraphs (b) and (c) to provide for more uniform regulations and for future expansion. The regulations are amended in newly redesignated paragraph (d) by adding new paragraph (d)(1)(xvii) to reflect the approval.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), use of salinomycin, roxarsone, and bacitracin methylene disalicylate Type A medicated articles to make Type C medicated feeds as provided in NADA 135–321 is limited to manufacture in a licensed feed mill.

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, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning May 29, 1997, because the supplemental application 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 application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new combination providing for a 34.1 g/t level of roxarsone.

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).

2. Section 558.550 is amended by redesignating paragraph (b) as paragraph (d), by adding and reserving new paragraphs (b) and (c), and by adding new paragraph (d)(1)(xvii) to newly redesignated paragraph (d) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(b) [Reserved]

(c) [Reserved]

(d) * * *