after ''000061'' the phrase ''and 059130''.

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–14103 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 520

Oral Dosage Form New Animal Drugs; Orbifloxacin Tablet

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 new animal drug application (NADA) filed by Schering-Plough Animal Health. The NADA provides for use of orbifloxacin for dogs for management of diseases associated with bacteria susceptible to orbifloxacin.

EFFECTIVE DATE: May 29, 1997.

FOR FURTHER INFORMATION CONTACT: John D. Baker, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed NADA 141–081 for Orbax™ (orbifloxacin) tablets for dogs for the management of diseases associated with bacteria susceptible to orbifloxacin. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of April 22, 1997, and the regulations are amended by adding new § 520.1616 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning April 22, 1997, because no active ingredient including any ester or salt of the active ingredient, has been approved in any other application.

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).

2. New § 520.1616 is added to read as follows:

§ 520.1616 Orbifloxacin tablets.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 to 7.5 milligrams per kilogram body weight.

(ii) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) *Limitations.* Administer orally 2.5 milligrams per kilogram of body weight once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. May be increased to 7.5 milligrams per kilogram if needed. For treatment of skin and associated soft tissue infections, administer for 2 to 3 days beyond cessation of clinical signs to a maximum of 30 days. For treatment of urinary tract infections, use for at least 10 consecutive days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–14107 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 520

Oral Dosage Form New Animal Drugs; Gentamicin Sulfate Soluble Powder

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 Agri-Laboratories, Ltd. The ANADA provides for the use of gentamicin sulfate soluble powder for use in swine drinking water for the control and treatment of colibacillosis in weanling swine and for swine dysentery.

EFFECTIVE DATE: May 29, 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: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–185, which provides for the use of Gen-Gard™ (gentamicin sulfate) soluble powder in swine drinking water for the control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

ANADA 200–185 is approved as a generic copy of the Schering-Plough Corp.'s Garacin® (gentamicin) soluble powder in NADA 133–836. The ANADA is approved as of April 30, 1997, and the regulations are amended in 21 CFR 520.1044c(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.

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.