Dated: November 8, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32345 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride 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 a supplemental abbreviated new animal drug application (ANADA) filed by Alpharma, Inc. The supplemental ANADA provides for reducing the preslaughter withdrawal time to zero days for use of lincomycin soluble powder in medicated drinking water for swine.

DATES: This rule is effective December 24, 2002.

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, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to ANADA 200–189 for Lincomycin (lincomycin HCl) Soluble requesting a reduction in the preslaughter withdrawal time to zero days for use of lincomycin soluble powder in medicated drinking water for swine. The supplemental ANADA is approved as of September 19, 2002, and the regulations are amended in § 520.1263c (21 CFR 520.1263c) 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under § 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 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 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: 21 U.S.C. 360b.

§ 520.1263c [Amended]

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (d)(1)(iii) by removing ''Nos. 046573 and 051259'' and by adding in its place ''No. 051259''.

Dated: December 5, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32343 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

Oral Dosage Form New Animal Drugs; Florfenicol

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 Corp. The NADA provides for use of a florfenicol concentrate solution to make medicated drinking water for administration to swine for the treatment of respiratory disease. FDA is also amending the regulations to add tolerances for residues of florfenicol in edible tissues of swine.

DATES: This rule is effective December 24, 2002.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141–206 for NUFLOR (florfenicol) 2.3% Concentrate Solution used to make medicated drinking water for administration to swine for the treatment of respiratory disease associated with several bacterial pathogens. The NADA is approved as of September 4, 2002, and the regulations are amended in 21 CFR part 520 by adding § 520.955 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulations are amended in 21 CFR 556.283 to establish tolerances for residues of florfenicol in edible tissues of treated swine and to reflect a current format.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 4, 2002.

The agency has determined under 21 CFR 25.33(d)(5) 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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 520 and 556 are 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: 21 U.S.C. 360b.

2. Section 520.955 is added to read as follows:

§ 520.955 Florfenicol.

(a) *Specifications*. Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

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

(c) *Related tolerances*. See § 556.283 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount*. Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis* Type 2.

(3) *Limitations*. Do not slaughter within 16 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.283 is amended by revising paragraph (b) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm).

(ii) *Muscle*. The tolerance for florfenicol amine (the marker residue) is 0.3 ppm.

(2) *Swine*—(i) *Liver (the target tissue)*. The tolerance for parent florfenicol (the marker residue) is 2.5 ppm.

(ii) *Muscle*. The tolerance for parent florfenicol (the marker residue) is 0.2 ppm.

Dated: December 13, 2002.

Stephen F. Sundolf,

Director, Center for Veterinary Medicine.

[FR Doc. 02–32341 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplemental ANADA provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

DATES: This rule is effective December 24, 2002.

FOR FURTHER INFORMATION CONTACT: Julia W. Punderson, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570, e-mail: *jpunder1@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, filed a supplement to approved ANADA 200–008 that provides for the use of BIO–MYCIN 200 (oxytetracycline injection) and OXY–TET 200 (oxytetracycline injection) as treatments for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of these oxytetracycline injectable solutions to lactating dairy cattle. The supplemental application is approved as of September 3, 2002, and the regulations are amended in 21 CFR 522.1660 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, 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 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) by removing in the eighth sentence ''000010, 059130, and 061623'' and adding in its place''059130 and 061623'', and by removing in the ninth sentence ''For sponsors'' and adding in its place ''For sponsors 000010,''.

Dated: December 4, 2002.

Steven D. Vaughn,

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

[FR Doc. 02–32276 Filed 12–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.