

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.

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(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]

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**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]

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**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.